IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY, : Civil No. 07-cv-3770-DMC

Plaintiff, :

v. : TRANSCRIPT OF TRIAL PROCEEDINGS

ACTIVIS ELIZABETH LLC, : VOLUME 3
GLENMARK PHARMACEUTICALS INC., USA,
SUN PHARMACEUTICAL INDUSTRIES LIMITED, :
SANDOZ INC., MYLAN PHARMACEUTICALS INC.,
APOTEX INC., AUROBINDO PHARMA LTD., :
TEVA PHARMACEUTICALS USA, INC.,
SYNTHON LABORATORIES, INC., :
ZYDUS PHARMACEUTICALS, USA, INC.,
:
Defendants.
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Newark, New Jersey
May 24, 2010

BEFORE:

THE HON. DENNIS M. CAVANAUGH, U.S.D.J.

Reported by
CHARLES P. McGUIRE, C.S.R.
Official Court Reporter

Pursuant to Section 753, Title 28, United States Code, the following transcript is certified to be an accurate record as taken stenographically in the above entitled proceedings.

s/CHARLES P. McGUIRE, C.S.R.

CHARLES P. McGUIRE, C.S.R.

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THE COURT: All right. In the matter of Lilly.

J A M E S R. J O H N S O N, called as a witness on behalf of the Defendants, and having been previously sworn, resumed the stand and testified as follows:

MR. BURWELL: Good morning, Your Honor. Scott Burwell on behalf of Plaintiff Eli Lilly and Company.

One minor housekeeping matter before we begin today.

Upon review of the transcript from Wednesday's session, we realized that a Trial Exhibit that had been moved into evidence at the close of the cross-examination of Mr. Goolkasian had not actually been discussed with the witness, so we would like to withdraw that exhibit from evidence. It's Plaintiff's Trial Exhibit 912.

THE COURT: Any objection?

MR. CLEMENT: No objection, Your Honor.

MR. BURWELL: Thank you, Your Honor.

MR. PARKER: Good morning, Your Honor.

THE COURT: Good morning.

As I recall, Dr. Johnson was in the middle of testimony on Wednesday. It seems like so long ago.

(Laughter)

MR. PARKER: That's correct.

THE COURT: So he is back on the stand, still under oath. Are you ready to proceed?

MR. PARKER: I am, Your Honor.

DIRECT EXAMINATION (CONTINUED)

BY MR. PARKER:

Q. Good morning, Dr. Johnson.

A. Good morning.

Q. Dr. Johnson, when we left off, you identified dose dumping as one of the challenges that one would encompass in developing a depot injection. Do you recall that?

A. Yes.

Q. Now, were there any other challenges that one could face when developing a depot injection in connection with -- well, developing a depot injection that would enable one to practice the claims of the '590 patent?

A. I'm not sure exactly what I described were the problems, but there are a number of problems. One seems to be initiation of release. A second might be a burst release on injection. Irritation is a very significant problem.

There's a number of problems.

Q. Can you just briefly explain what you mean by the initial rate release?

A. Quite often when you inject with these systems, you get sort of a burst release. With Leuprolide, for example, is probably the most commonly used one, I think you release somewhere between 20 and 40 percent of the drug within the first two, three days. It's something like that. So that's

pretty high. In the case of Leuprolide, it may not be a significant problem because that jolt is useful, is my understanding.

Q. Now, why is it important to work out the initial release rate?

A. Because at any time you're dosing these systems, what you're really trying to do is, the reason for doing most of them is, you're trying to achieve some sort of constant release rate so that you get a predictable release and you get a predictable effect.

Q. Okay. And when you say constant release rate over a period of time, how much -- what period of time are you referring to?

A. Whatever the -- whatever you've decided you were trying to make. If you're making a seven-day one, you want to release continually over seven days; if it's a month, you want a month.

Q. And just generally, how is it that one of ordinary skill in the art as of January 1995 would go about working through or working out the initial release rate?

A. Typically, we look at -- it's some sort of in vitro drug release system.

Q. Now, in working out that initial release rate, is that an iterative process, to your knowledge?

A. It's typically a difficult process because you can

work out -- you typically work out two or three different release rates. Then you test it in animals and you see, can you make a correlation. If you can make a correlation then you may go to the next step. If you can't make the correlation, you go back and repeat it.

Q. All right. Now, Dr. Johnson, just referring to slide 22, last Wednesday, when you were describing the preliminary formulation and excipient selection stage of making an aqueous suspension, which is over here on slide 22, the aqueous suspension depot injection, how long would it take to conduct the same step, the preliminary formulation and excipient selection step, for the base when making a -- when making an oil hydrophobic solution?

A. It really takes quite a long time. If you're very lucky, you might do it in six months. Otherwise, it would probably take up to a year.

Q. Now, what about with respect to microparticles on slide 22?

A. They would be probably more difficult because you're controlling the release. You've added dissolution of the particle, and the particle size is important, in addition to releasing into the dosage form, which would subsequently release into the body.

Q. Now, Dr. Johnson, with respect to the opinions that you provided the Court last Wednesday and the ones going

forward you're providing today, will you be giving these opinions from the perspective of one of ordinary skill in the art?

A. When I did these charts, I tried to do this from the perspective of people with like a pharmacy degree, three to five years' experience, or a related technical degree with similar experience.

Q. Which is basically how you define one of skill in the art?

A. Correct.

Q. Now, Dr. Johnson, generally, when preparing any dosage form, does it require selecting the appropriate form of atomoxetine?

A. Could you repeat the question?

Q. When preparing any dosage form, does it require selecting the appropriate form of atomoxetine?

A. Correct.

Q. Now, can atomoxetine be in the form of a freebase?

A. Yes.

Q. Now, is the freebase in the form of an oil, to your knowledge?

A. From the earlier -- yes, from reading the patents, it appears to be, but I don't have any of that --

Q. I'm sorry?

A. I don't have any atomoxetine base so I can identify it

as an oil, but from reading the patents, it appears that it should be -- it's described as an oil.

Q. Now, can atomoxetine be in the form of a salt?

A. Yes.

Q. And when it's in form of a salt, is it a solid, liquid? Is it an oil?

A. It should be a solid.

Q. Now, what are the various salt forms of atomoxetine that a person of ordinary skill in the art as of 1995, January 1995 would have had to consider in selecting an appropriate salt form of atomoxetine?

MR. BAJEFSKY: Objection, Your Honor. This is the same slide that we objected to last week, and it's just not in his report.

THE COURT: It's just not what?

MR. BAJEFSKY: It's not in his expert report.

THE COURT: Counsel?

MR. PARKER: Your Honor, it is in his expert report. What we've done is, we took out the banner, which had the breadth of the claim.

THE COURT: Wait. Did you say it is in his expert report?

MR. PARKER: Yes, it is.

THE COURT: Where is it?

MR. PARKER: Okay.

THE COURT: Point it out to counsel.

MR. PARKER: Okay. Sure.

(Off the record discussion)

MR. BAJEFSKY: That's it?

MR. PARKER: Well, then we also have in paragraphs 41 and much of the other paragraphs where he talks about salt selection in developing the various dosage forms.

MR. BAJEFSKY: Your Honor, the part that was pointed to does not list those salts. He never pointed to those salts in the expert report, and if --

THE COURT: This is a factual situation. I mean, it either is or is not in. I don't know how we can have a disparity.

MR. PARKER: Right. Your Honor, in your binder, you have just DTX --

THE COURT: In the?

MR. PARKER: In the witness binder.

THE COURT: Go ahead.

MR. PARKER: We have DTX-3.

THE COURT: DTX-3. Yes.

MR. PARKER: Which is the '081 patent, and again, in his expert report, he refers to tomoxetine in its freebase form as being an oil -- this is in his expert report on paragraph 31 -- but when conjugated as a salt, it forms a white crystalline solid. And he refers to the '081

patent that's now before you, Your Honor.

THE COURT: Right.

MR. PARKER: And refers to column two, lines 59 to 61.

THE COURT: Yes?

MR. PARKER: And there, it says: "The compounds of this invention in the form of their freebase are high boiling oils, but white crystalline solids in the form of their acid addition salts."

And right above that paragraph are the salts that we have listed on the slide. And throughout his expert report he talks about salt selection.

THE COURT: So you're saying they're listed in there, just not in this form?

MR. PARKER: They're listed in the patents exactly how it appears on the slide.

THE COURT: They're listed in --

MR. PARKER: In other words, if you look at, okay, on column two --

THE COURT: Yes, I'm there.

MR. PARKER: Okay. So that when we -- it refers to the acid addition salts, but the acid addition salts are identified right above that paragraph.

THE COURT: Okay. They're not listed in this form. They don't look like that.

MR. PARKER: Well --

THE COURT: I'm not saying that's fatal.

MR. PARKER: Right.

THE COURT: I'm just saying they don't look like that.

You're saying they're listed, just not in that form.

MR. PARKER: Exactly.

MR. BAJEFSKY: Your Honor, he did not refer to those salts at all in the expert report. He just referred to, as Mr. Parker pointed out, lines 59 to 61. He never suggested for a moment at any point in his expert report that atomoxetine could be made using all of these salts. I never had an opportunity to examine him on it at his deposition. I might well have done that had he made an allegation like that in his expert report. It was not in his report.

THE COURT: So you're saying not only is it not in his report, you've never heard him talk about this before?

MR. BAJEFSKY: That's correct, Your Honor.

THE COURT: What do you say to that?

THE WITNESS: I believe I mentioned insoluble salts, and many of these would be insoluble salts. For some of these dosage forms, it's best if I make an insoluble salt. So I go through this list because they're acceptable

pharmaceutical salts and take one of these and make that salt.

THE COURT: Why didn't you just put this listing such as this attached as an exhibit in your report?

THE WITNESS: I didn't think of it.

MR. PARKER: If I may. He adopted Dr. Shukla's report, essentially, he didn't prepare the report.

THE COURT: I wasn't saying that as blaming him.

MR. PARKER: Oh, okay.

THE COURT: I was just inquisitive as to why he didn't.

MR. PARKER: Your Honor, we did attach the '081 patent as an exhibit to Dr. Shukla's report.

THE COURT: Yes, but you know, I realize this is technical, but as a practical matter, it's not fair, especially when dealing with pointed opinions of experts, to just attach something and say, now anything and everything in there has to be considered as part of that. I mean, I think there's a certain amount of obligation on behalf of the expert to be somewhat specific as to what it is they're referring to so that the other -- I mean, that's the whole purpose of expert reports, so that the other side can make a determination and review it and know what they're doing.

MR. PARKER: And I agree, Your Honor, but in the

report as well, the expert report, when it's laying out in discussion the various dosage forms, there is a step where it's a salt selection step, just like the atomoxetine salt, and we refer back to the only patent in the prior art that actually lists all these salts of atomoxetine. And the cite, we actually cite a portion --

THE COURT: Well, why don't you just deal with his testimony and talk about the salts without having all this list of them? We understand that this list is in the universe. Why do we have to have this whole list up there?

MR. PARKER: Okay, Your Honor. Thank you.

THE COURT: So I'll sustain the objection.

Go ahead.

BY MR. PARKER:

Q. Dr. Johnson, in your review of the prior art, were you able to -- does the prior art -- let me back up.

Does the prior art in your review identify the available salt forms of atomoxetine?

A. Yes.

Q. And do you have your witness book in front of you?

A. Yes.

Q. And I refer you to DTX-3.

A. Correct.

Q. Now, is that a reference you reviewed as part of your analysis?

A. Yes.

Q. And upon your review of that patent, which is DTX-3, U.S. Patent 4,314,081, does it identify the list of the salt forms that atomoxetine could be prepared?

MR. BAJEFSKY: Objection, Your Honor. He's just showing the slide again without putting the slide up.

THE COURT: Well, but did you say that the '081 patent was listed in his report?

MR. PARKER: Absolutely, Your Honor.

THE COURT: Well, if it was listed, I can't preclude him from talking about it. It's there.

MR. BAJEFSKY: Well, but he cited it for a very specific point, Your Honor, and it was the lines that Mr. Parker pointed to. He didn't cite it for the entire disclosure in the patent. There's a lot of stuff in the patent that has nothing to do with his report, and these salts have nothing to do with the report, Your Honor.

THE COURT: No, I'm going to let him testify.

Go ahead.

BY MR. PARKER:

Q. Dr. Johnson, can you tell us where in the '081 patent you found a list of pharmaceutically acceptable salts, and can you identify where you found it by column and line number?

A. Page -- column two, line -- I guess 31 to 54.

Q. And if you look also, Dr. Johnson, just focusing on pharmaceutically acceptable salts, which I believe is line 43, can you just identify where in the patent -- or column 2, line 43 where in the patent it lists pharmaceutically acceptable salts?

THE COURT: Wait. I didn't catch that question.

Q. Where in that patent it lists pharmaceutically acceptable salts?

THE COURT: Well, didn't you just say line 43?

MR. PARKER: I said line 43.

A. I said line 2 -- at 41, it says "pharmaceutically acceptable salts of amine base." Then in 40-something here, it starts listing the actual salts themselves.

Q. And where does that end, the list?

A. Fifty-nine -- 58.

Q. Again, just staying on salt selection, I believe, Dr. Johnson, when you reviewed the '590 patent, were you able to -- did it have any information about salts in the '590 patent?

A. Yes.

Q. And can you tell us what information was in the patent?

A. It was a list of a variety of salts, over 60 salts that I might be able to choose from as -- when I wanted to make a different salt for atomoxetine.

Q. Where in the patent does it talk about salts? Can you tell us that?

A. Column 2.

Q. I'm sorry, in the '590 patent.

A. In the '590 patent.

Q. That would be --

A. Oh, that's on the first page.

Q. DTX- -- '590 --

A. Yeah.

Q. I'm sorry. DTX-1, which is the '590 patent?

A. Correct. It's on column 1, line 55: "Tomoxetine is a well known drug," it's a phenylpropylamine. "It is regularly used as a salt, and salts are included in the term tomoxetine as used here."

Q. Okay. That was column 1, lines 54 to 57?

A. Yes.

Q. And that was DTX-1.

Now, Dr. Johnson, we've reviewed this portion of the '590 patent. Did you come to any conclusions?

A. That I could use tomoxetine in any salt form or base.

MR. PARKER: Slide 24. I apologize.

Q. Let's move on to a new dosage form, Dr. Johnson.

First of all, with respect to this slide, slide 24, and also slide 25 -- Dr. Johnson, with respect to slides 24 and 25, were these slides prepared pursuant to your

direction and supervision?
A. Yes.
Q. And do these slides accurately reflect based on your knowledge and experience the steps one skilled in the art would have undertaken to prepare a transdermal patch?
A. Yes.
Q. And you had this slide prepared for your testimony today? Did you have this slide prepared?
A. Yes. Yes.
Q. Now, Dr. Johnson, did you find anything in the prior art regarding formulating a transdermal patch comprising atomoxetine or a similar compound?
A. No.
Q. Now, with respect to slides 24 and 25, are you illustrating how one -- in these slides, are you illustrating how one of ordinary skill in the art would prepare a viable dosage form?
A. Yes.
Q. And in that context, what do you mean by viable dosage form?
A. One that's suitable for carrying out claim 1.
Q. Claim 1 of what; the --
A. To determine whether or not you could -- for use in delivering an effective dose of atomoxetine to a patient.
Q. And when you refer to claim 1, are you referring to

the '590 patent?
A. Correct.
Q. What is a transdermal patch?
A. It's where you put medicament in a device or a -- that's placed on the skin. And the drug actually leaches out of that device in -- through the skin, into the bloodstream.
Q. And after the drug transports through the skin, where does it go?
A. It goes into the bloodstream.
Q. Have you yourself ever made a transdermal patch?
A. Yes.
Q. And can you just describe the type of patches you made?
A. We did work with corn pads, which were adhesives covered with salicylic acid and then it diffuses out into the corn area. And we did another one. We were looking at fungal nail, and we first looked at penetration through the nail bed of the antifungal, and then we took some nonwoven material and saturated it with the drug and a solvent which would penetrate the nail bed and then put an adhesive barrier over that.
Q. Now, do you consider yourself as a person who is highly knowledgeable with respect to what it takes to develop a transdermal patch?

A. Yes.
Q. Now, let's just, if you can, Dr. Johnson, focus on slide 22, I believe the first step that you've identified.
I'm sorry. Slide 24.
The first step you've identified is selecting the form of atomoxetine. Do you see that?
A. Yes.
Q. Okay. Now, does the patent, does the '590 patent provide any guidance in making any selection of a particular salt that could work in a transdermal patch?
A. No.
Q. So how does one skilled in the art go about selecting an appropriate form of atomoxetine for a transdermal patch?
A. Repeat the question, please.
Q. Yes, sure.
How does one skilled in the art as of January 11th, 1995 go about selecting an appropriate form of atomoxetine for a transdermal patch? Referring to the slide.
A. The way we looked at it, we looked at it several different ways. One is, we tried to determine whether or not you'd want to use a base or a salt, and so we thought that the easiest way was to try to see if we could get the soluble salt in the solvent and/or adhesive matrix which would then -- you could put on the skin and it would diffuse

out through the skin.
Q. Now, whether you're selecting a base or a salt form of atomoxetine, does irritation have any effect at all in that decision?
A. Yes.
Q. Can you explain how that is?
A. One of the problems with transdermal patches is wear, in wear tests, one just keeping them on, but if you keep it on for -- you know, some of these patches they keep on for more than -- more than a day, the problem of irritation is significant. So you try to make it so that the drug won't irritate it, the adhesive won't irritate, or any of the adhesive layer binding the transdermal to your skin won't irritate.
Q. Now, would atomoxetine hydrochloride be an appropriate salt for a transdermal patch? If not, why?
A. I don't believe it would be.
Q. And why is that?
A. It probably would -- it's a salt, and it's too soluble and too hydrophilic, and it would not -- probably be irritating.
Q. So, then, looking at the selecting form of atomoxetine step, where would you begin?
A. I began with the base, because it would be hydrophobic, and we could put that in adhesive and see

whether we could get a solvent or adhesive solvent system which we'd penetrate.

Q. Now, at what point would you know whether or not the base is the appropriate form for a transdermal patch?

A. Whether we could get it transferred to some kind of skin or barrier into -- we did dissolution studies, essentially, --

Q. Okay.

A. Through a barrier of some kind, which would simulate the skin.

Q. So now referring to the slide 24, can you just tell us what tests are up there that one of ordinary skill would conduct or would have conducted? And you can use your pointer as well.

A. Well, we take the base, and we have to confirm that it's pure because we don't want to repeat all this work with an unpure material. And we test the solubility of different solvents. We look at the purity, we look at the pH solubility; in other words, if this matrix has any hydrophilicity, we might adjust the pH slightly, too, to keep most of the base in a more hydrophobic state. And we look at these solvent studies that might be compatible with some adhesives. Then we'd try to look at tests to look at skin permeability through usually a Franz cell or some kind of dissolution device where you'd have a cell in the bottom,

you have the drug, and you put it on a layer, and the layer could be a semipermanent membrane or it could be some kind of skin layer, and what you try to do with this is determine how fast it will go through this layer into this receiver compartment, and the receiver compartment is essentially the bloodstream.

Q. And, Dr. Johnson, just back up a little bit. Why does one skilled in the art need to conduct the stability testing?

A. Because you don't want to administer a drug which is degraded.

Q. And how does one skilled in the art, how would they have conducted the stability testing?

A. In this case, you'd conduct the stability test in the matrix ingredients that you might eventually use to -- in your layer that you put on the skin.

Q. Now, I'm sorry, I meant to say solubility, stability testing which is in the box there, so --

A. Okay. We'd look at the solvents we'd think we'd use. We put these solvents at various conditions. We might subject them to oxygen, heat, light, and see whether or not there's any degradation over a period of time.

Q. Now, why does one skilled in the art need to conduct the purity testing on slide 24?

A. You have to have a drug -- the drug that you

administer has to be intact, it can't be degraded.
Q. And how does one skilled in the art go about conducting purity testing?
A. You develop analytical techniques for degradation products in the active raw material.
Q. Now, when you say you have to develop analytical techniques, is there anything out there in the prior art that is directed to analytical testing for something of a compound like atomoxetine or something similar?
A. I didn't.
MR. BAJEFSKY: Objection, Your Honor. It's not in his expert report. None of this is in his expert report, Your Honor.
MR. PARKER: Your Honor, it is. I mean, the entire expert report is focused on developing these various dosage forms. And we have paragraphs, and I'll go through each one, if I have to, with respect to each step.
THE COURT: If there's new theories that aren't in the report, that's one thing; but certainly there are inferences that can be drawn from statements in expert reports, and he can certainly expand to some degree upon that which is in the report.
MR. BAJEFSKY: I understand that, Your Honor, but there was nothing in his expert report about whether there were things in the prior art that would enable him to

determine whether or not something was suitable. It's not in his expert report.

THE COURT: But wouldn't that be part of the whole basis of this argument?

MR. BAJEFSKY: Okay. I'll withdraw it, Your Honor.

THE COURT: Continue.

MR. PARKER: Could you read a back the last question.

(Record read)

A. I -- I don't know. I haven't looked.

Q. Well, could you just explain a little more, what do you mean by developing analytical techniques? What do these techniques do? What's their function?

A. Their function is to determine the purity of your compound.

Q. Now, why does one skilled in the art need to conduct pH solubility testing?

A. Because you want to make sure that if you do adjust the pH that it's still stable.

Q. So it's possible that changes in pH could affect stability of the compound?

A. Correct.

Q. And how does one skilled in the art conduct the pH solubility testing?

A. You would put it in the media or solvent that you think is -- and you can adjust pHs to different levels. Probably you'd go up to eight, you wouldn't want to go higher, seven, six, five, maybe, and just determine how the stability and solubility change.

Q. Now, you also have on slide 24 solvent studies in connection with your analysis of the base. Just, why would one skilled in the art have to carry out solvent studies?

A. You have to get it through the skin, so you need some media to get it through the skin, and so you'd pick solvents which would penetrate the skin or penetration enhancers which would penetrate the skin and carry the drug through the skin into the tissue, where it can then be absorbed into the bloodstream.

Q. Now, again, dealing with slide 24 as you were talking, as you were testifying as to the analysis of the base, you have arrows and you have other -- green arrows indicating yes and orange arrows indicating no. What was it you were trying to convey in this aspect of the process?

A. It's iterative.

Q. Could one of ordinary skill in the art predict without conducting any of these tests whether or not an atomoxetine base would be suitable for a transdermal patch?

A. Say that again, please?

Q. Could one of ordinary skill in the art predict,

without conducting any of these tests that we just talked about, could they predict the suitability of atomoxetine base for a transdermal patch?

A. No.

Q. Now, based on your experience, Dr. Johnson, how long would it take for a person of ordinary skill in the art as of January 11th, 1995 to determine whether or not the base form would be suitable for engaging in the next step of the -- what you have down here as the skin permeability/irritability step? So how long would it take to go through the process here that you described with respect to the base dealing with the various testings, solubility/stability, purity, pH solubility and solvent studies, how long would it take you to complete this phase?

A. It really depends on the base. When we looked at lidocaine base for a topical where we could spray on a solvent system, it's actually transdermal because it has to go through the skin, that was fairly easy, we could do that in six months. But the antifungal is a very difficult material to both solubilize and transport, and I know we spent more than a year.

THE COURT: Wait. Did you say more than a year?

THE WITNESS: Yes.

Q. And based on your experience and your knowledge of atomoxetine, would you still estimate how long this would

take, that particular aspect of the testing?
A. It's say probably not less than six months and probably not more than a year. I don't think it would be as difficult as that antifungal.
Q. Okay. So now once you've evaluated the base form of atomoxetine, what is the next step one skilled in the art would have to conduct?
A. You'd be looking at the skin permeability and irritability, because if the parent compound is irritating, then it's not a good choice.
Q. Okay. So what would skin permeability studies entail?
A. As we discussed, when we were looking at these, we tried to translate these results in these first four diamonds into a system we could then run a dissolution study and look at the permeability through a semipermeable membrane or some kind of skin layer.
Q. And what would skin irritability studies entail?
A. We'd probably do a patch test on rats or guinea -- probably guinea pigs, where we'd take the drug, we'd mix it in oil, we'd put it on the skin, and we'd cover it up with material which is impermeable to evaporation. In other words, it's a closed patch test. You really look at how seriously this would be -- you overemphasize the irritability if it exists so you can pick it up.
Q. Well, just going back to transdermal formulation

systems, as of January 11th, 1995, what transdermal systems were available for drug delivery?

A. There are a multitude of them.

Q. Well, do you recall any of them? Reservoir, would that be one of them?

A. There's Nitroderm, there's a nitroglycerin patch.

Q. Were there multiple systems?

A. Yes.

Q. Over here, I believe, Dr. Johnson, we have multiple systems. Are those the multiple systems for transdermal patches that were available as of January 11th, 1995?

A. That's my understanding.

Q. And you have reservoir, adhesive diffusion, and micro-reservoir?

A. Right.

Q. Now, would one skilled in the art undertake any one of these formulations first?

A. Pardon me?

Q. Would one of ordinary skill in the art undertake in the development of the transdermal patch, would they take any one of these systems first?

A. You're trying to do the easiest one, and the adhesive layer -- if you can put an adhesive layer and have that controlled release good enough, that's probably the easiest one. I believe that's the nitroglycerin one.

Q. And just so we're clear, what are the components of an adhesive diffusion system?

A. You have a backing. Then you have a layer of we'll call it adhesive. The adhesive would be kind of a -- probably a flowable material that would conform to the skin and actually hold that layer onto the skin. Then you have another barrier on top of the adhesive which you peel before you put it on.

Q. And now, are there any excipients that would need to be evaluated for an adhesive diffusion formulation?

A. Well, we'd have to look at a solvent system that's compatible with an adhesive and that would allow the drug to penetrate through the skin.

Q. Now, again, just referring to slide 25, I believe you have a step, excipient compatibility step. Do you see that?

A. Yes.

Q. Okay. Now, you've laid that out in connection with developing an adhesive diffusion system; is that correct?

A. Right.

Q. Okay. Now, if you could, I see you have three tests that are involved in the excipient compatibility analysis. You have particle size, stability, you have in vitro diffusion cell test.

Why does one skilled in the art need to conduct a particle size analysis?

A. You probably wouldn't unless you're using an insoluble drug which was a particulate. With the base, we're trying to get that dissolved in the adhesive layer, so we probably wouldn't do the particle size, but let's say where we're putting in the particles in the matrix which then slowly dissolve, we control particle size because that's one of the rate-limiting steps.

Q. So if the base was not an appropriate form of atomoxetine and you were using a salt form of atomoxetine, then you would have to consider the particle size?

A. Right.

Q. And how does particle size -- what role does particle size, if any, have in developing --

A. This solution rate typically is controlled by the particle size.

Q. So determining --

A. Small, like small particles will dissolve faster than big particles.

Q. And is there a situation with release rate in connection with particle size that you need to adjust or have to test?

A. Right. We would select particle sizes and look at the release rate from different particle sizes.

Q. And how does one go about carrying out the particle size test? In particular, how does one go about selecting

the appropriate particle size?
A. We use different measuring equipment. Just the size -- particle size is usually fairly difficult. We may use a dissolution technique. We may use a laser counterpart technique. We have a new one that we've been looking at called the particle insight where it takes pictures of all the shapes and sizes, and it's kind of unique in that it allows you to evaluate unexpected results better.
Q. Now, was that technique available in January of 1995?
A. No. No. No.
Q. Okay. So what would one of ordinarily skill in the art, what would they have done as of January 11th, 1995?
A. He could have used a laser particle counter. He could use dissolution, or he could use a Coulter counter. There's a variety of instruments that were available.
Q. Okay. Now, just continuing on the excipient compatibility step on slide 25, with respect to the stability testing, can you just tell us why would one of ordinary skill in the art carry out those tests and how would they go about doing it?
A. They would take the matrix system that we had and would put it in different conditions and look at the -- the -- if the drug remained stable.
Q. Now, again, why? Why would they have to conduct that? Why is stability important?

A. Because you really can't administer an unstable compound. It has to be intact.

Q. Now, again, looking on the same, again, dealing with the excipient compatibility portion of your slide on slide 25, can you tell us, why would one of ordinary skill conduct in vitro diffusion cell test and how would they go about doing that?

A. Well, they would make the system as -- at probably different variance concentrations, and you'd probably put it -- you'd put it on one of these membranes, and the membrane is sitting on top of a liquid; you stir the liquid and measure how much transports from that system into the liquid.

Q. Now, when you say "membrane," are we talking about pieces of skin or --

A. Sometimes you use pieces of skin. We had some mouse skin models. But you can use semipermeable membranes as well, which are plastics, let's say.

Q. And these were the type of tests that were available prior to 1995?

A. They were commonly used.

Q. Now, Dr. Johnson, as you go through the process of assessing the excipient compatibility in developing an adhesive diffusion, is that -- well, you have arrows, and you have the yes and noes. Again, I just want to ask you,

what were you trying to convey there?
A. What you do is, you do these studies, and then you changes things, you do them again, you change things, you do them again. They're mostly iterative steps.
Q. Okay. So now before we get to the next step, so just going through, again, focusing on adhesive diffusion system, and you've gone through -- now you're going through the excipient compatibility phase of the development here, how long would this particular process take one of ordinary skill in the art in January 1995?
A. Probably three to six months.
Q. Now, again, could one of ordinary skill in the art predict whether or not one excipient or another is compatible with the active ingredient without conducting any tests?
A. Not generally, no.
Q. I'm sorry, can you repeat that?
A. Not generally, you can't. You can predict certain things. By this time we will have enough information to make some predictions because we're doing all that study in the front, you know, the first half, so we have -- at this point, we have enough information to make some predictions.
Q. But with that, would one of ordinary skill in the art still have to conduct some -- carry out at least some aspect of the testing?

A. Right, because we don't know how it's going to affect the release.

Q. You don't know how it's going to affect the release?

A. Correct.

Q. And how it affects the release would impact whether or not a certain quantity of the testing would be carried out?

A. Well, it would affect whether or not we are close enough to start looking at animal studies or animal models.

Q. Now, does the prior art provide any correlation between atomoxetine penetration through the skin?

A. Repeat the question, please?

Q. Does the prior art provide any information with respect to the correlation of atomoxetine penetration through the skin?

A. No.

Q. And none of that information is found -- is any of that information found in the '590 patent?

A. No.

Q. Now, we didn't get into -- well, let's just focus just on the micro-reservoir and the reservoir system that's on top of slide 25.

A. Right.

Q. Now, is the quant of experimentation and the unpredictability that you described in connection with the adhesive diffusion formulation when you're assessing

excipient compatibility, is it the same with respect to the reservoir system? Would it be the same?

A. Reservoir is probably more difficult.

Q. And why is that?

A. Because you have more components.

Q. I'm sorry?

A. You have more components. It's a more complex system.

Q. What other additional components do you have?

A. You'd have a reservoir which is distinct from the adhesive layer. So now we've got another diffusional component where it's got to diffuse out of the reservoir through the adhesive to the skin.

Q. And with respect to a micro-reservoir --

A. That would be probably comparable.

Q. Comparable to what?

A. The reservoir.

Q. Now, just for the -- could you just -- can you describe the differences -- I mean, we have three systems, reservoir, adhesive diffusion, and micro-reservoir. I mean, can you just generally describe the differences between the three systems just to get an understanding as to why they're separated out as being different?

A. I separate them mainly because the reservoir in the middle system, adhesive system is the adhesive. The reservoir on these other systems -- and they may be multiple

reservoirs, may be one, may be two, maybe be three, where the drug is actually in different layers, and these might be like sandwiches that are put together, in other words, which layer might have more drug, so it would -- so you can actually program the release.

Q. Have you ever heard the reservoir system being analogized to a ravioli?

A. No.

Q. I have.

THE COURT: What about that?

(Laughter)

MR. PARKER: I had a case a long time ago dealing with reservoir systems, and it looked like a ravioli. The inside, the cream cheese was the active ingredient that went through, and that was the analogy made.

Q. Okay. So in developing a transdermal patch, now, once you've prepared a suitable preliminary formulation, so to speak, what's the next step one of ordinary skill in the art would have had to conduct --

THE COURT: Wait a minute. Who puts cream cheese in a ravioli?

(Laughter)

MR. PARKER: I'm sorry, you're right. My mother would kill me if she heard me say that. Ricotta, or ricotta.

THE COURT: Go ahead.

Q. All right. So in developing a transdermal patch, once you've prepared a suitable preliminary formulation, what is the next step one of ordinary skill in the art would have to conduct?

A. You really now -- you've really got to go to an animal at this point and make sure that your in vitro system is actually rational. So you usually like to go to some kind of -- it could be a rat model, or maybe you need a little bigger, more scale, you can use a guinea pig, and you make a primitive dosage form of the adhesive backing layer that simulates your dosage form, and you look at the penetration rate in a live animal, and then you do a PK on this. You take blood levels from the animal and look at the relationship between transport and blood level. So you can estimate dose release per given area, because these things all go out of a patch. They all -- you know, maybe one inch square or two inches square, but it's all coming out of this patch. You've got to relate the size of that to how much transports into the body.

Q. Now, you mentioned PK again. What does that refer to?

A. It refers to a measurement of drug in the blood, and we relate that to the dose in the transport.

Q. Now, you also have mentioned the irritation. So why would one skilled in the art assess irritation, and how

would they go about doing that?
A. That really is going to define whether or not this is a viable way to try to do this.
Q. Now, in carrying out these animal PK studies and the irritation study, approximately how long would that take one skilled in the art in January of 1995?
A. Around three months. That's assuming by this time -- what you do in parallel, you would also develop a blood level method.
Q. Excuse me?
A. You'd need a blood level method so you can measure the drug in the blood. So you'd be doing that during one of these earlier stages so that you'd have it ready when you have to actually do the PK study.
Q. And what do you mean by blood --
A. You have to be able to analyze the drug in the blood to determine how it's released.
Q. Now, just going down to your next step -- and by the way, you have the circular arrow next to the animal PK study and irritation in your slide 25. What was that intended to convey?
A. That these kind of go back and forth. If you get a no, you've got to repeat it. If you get a yes, you can proceed.
Q. Now, let's just discuss -- well, let me back up.

Now, once we've refined the formulation -- I'm sorry. Once we finish the animal studies, the next step -- can you tell us what the next step is?

A. What we want to do is -- now we know how much is released per unit area. Now we have to put it on a human, and so we have to refine the formula to different sizes with the correct amount of drug in that patch so that on release, we'll have a good idea how much is going to be released per hour per unit area, like one milligram per square inch per hour, or some designation or some -- we'd have to grade it some way. So we then have to actually fabricate the patches so we can do the human study.

Q. I'm sorry, you had to fabricate what?

A. The patches so that we could actually do the human study.

Q. Did you also have to conduct an adhesion test or --

A. Yes, we do that as part of it, but --

Q. Is it also --

A. If it won't adhere to the skin, it won't work. So we do an adhesion study as swell.

Q. Pouch integrity; is that a factor?

A. Yes.

Q. And why is that a factor?

A. Because it has to -- the package has to retain integrity, but we really don't study that this much because

these are mostly handmade. They're to see whether or not you can get the right transport.

Q. Now, and how do you go about conducting in vitro tests?

A. We put -- we continue to use that as a quality standard. In other words, we get a test -- if we make 10 patches, or 20 patches, or whatever we make, we've got to make sure that once we refine the formula, we're still getting the same relative release rate.

Q. And what do you use as the medium, or what would one of ordinary skill in the art use as the medium?

A. We often used a phosphate buffer, but I think you can use other media as well.

Q. With respect to not so much the buffer, the medium, I meant the barrier under which you're looking to see if the drug is going through into the -- you know, is it going through the skin or not?

A. Probably use a semipermeable membrane or something like that.

Q. Now, again, going to refine formulation step, is that also an iterative process in your view?

A. Yes.

Q. And any idea how long that would take one of ordinary skill in the art in January of 1995?

A. The human PK, I would guess let's say six months.

Q. No, the refine formulation step.
A. That would probably take one to three months. Probably three months, because we've got to do some stability on it as well to make sure it's not changing.
Q. And with stability, I know you talked about that before in connection with the depot injections, but just to move things along, did that also involve looking at the effect that heat, light could have on the formulation?
A. Yes.
Q. Oxidation?
A. At this point, we would -- we would know -- at this point, we would already know if oxidation's an issue.
Q. Just turning to the reservoir system, the micro-reservoir system, is the amount, is the quantity of experimentation, and -- let me back up.
With respect to refine formulation, can one of ordinary skill in the art predict how to refine the formulation without conducting any tests?
A. No.
Q. Now, with the amount of -- with the quantity of experimentation and the level of unpredictability, if you look at the -- in connection with the reservoir, would that amount of quantity of experimentation and level of unpredictability be the same as it would be for adhesive diffusion when you're looking at the refine formulation step

in slide 25?
A. It might be more difficult to refine it.
Q. And why is that?
A. Because it has more components.
Q. Excuse me?
A. There are more components to affect the release.
Q. And what about micro-reservoir; would that be more, or less?
A. That would be similar to the reservoir system.
Q. All right. So now that you've refined the formulation, can you tell us what the next step is, would be?
A. We would do the human PK studies and finalize what the release rate would be and what the transport rate relative to the blood level is.
Q. Okay. So down here, we're still looking at -- well, you said human PK, studies and you also have irritation. What do you mean by irritation?
A. We would look and see whether it's irritating the skin of the subject.
Q. Now, you have dose range study for patch size. Can you just elaborate on that? What do you mean by that?
A. Again, we need to know how much drug is transported through the skin per hour per square inch so that we can arrive at units that we will try to confirm when we do a

blood level study. At this point, we don't know what the dose is because we have no information on the dosing related to blood level.

Q. And how long would these human PK studies and irritation studies take?

A. I think it would be in the range of six months.

Q. Also, you have a circular arrow next to that. Can you just tell the Court what you intend to convey?

A. If it doesn't work, you've got to do it again.

Q. And so after you've carried out these human PK studies and the irritation study on slide 25, after that's been completed, what then would one of ordinary skill in the art go about -- what's the next step?

A. We would take the patches and put them on people to see if we could get efficacy.

Q. And why do you have to determine whether or not there's efficacy?

A. That's to fulfill the claim 1 in the practice of the invention.

Q. And what is it about claim 1 that requires that in your view?

A. It's a method of treatment for ADHD, and probably you'll be doing four- to six-week studies to try to determine if there's efficacy.

Q. When you say four- to six-week studies --

A. Because it's a chronic -- it's a chronic condition which requires multiple treatment or treatment for sustained periods of time to determine efficacy.

Q. Now, does the claim also recite the phrase "effective amount"?

A. Correct.

Q. And does that have -- did that have any influence on your analysis?

A. Right. We don't know what the effective amount is from a transdermal system.

Q. Now, in your experiences, Dr. Johnson, based on your knowledge, when developing a transdermal patch, what are some of the challenges that one of ordinary skill in the art would encounter?

A. Trying to determine whether or not you can actually make a patch to get enough drug through fast enough so that this could be a viable way to dose the compound.

Q. What about --

A And whether or not it would be safe enough to do.

Q. What about an issue of release rate?

A. That's very important.

Q. Can you explain why that's important?

A. Because that determines -- if it isn't transported -- if it's eliminated from the body faster than it's transported into the skin, then you don't ever achieve any

effective blood level.

Q. Now, you also mentioned size of the patch could be an issue. Is that correct?

A. Correct.

Q. Can you explain how that --

A. Well, you know, if the patch is too big, people won't wear it. It's not a back plaster. If it's a back plaster, then they can wear it. But let's say it would be two by four inches or two by six inches. If you can place it in an area where the absorption is sufficient -- in other words, some of these patches you can place right behind the ear because that's a very absorptive area for like scopolamine. That will go through the skin very quick. But you can't put a four by six inch plaster under your ear, so you've got to find places where you can put it which transports fast enough so it could be used.

Q. Now, Dr. Johnson, based on your consideration of the Wands factors as you pointed out, as you set them out last Wednesday, have you formed an opinion as to whether as of January 11th, 1995, undue experimentation would have been required by a person of ordinary skill in the art to prepare a transdermal patch comprising an effective amount of atomoxetine in some form to treat ADHD?

A. Yes.

Q. And what is that opinion?

A. It would take undue experimentation.

Q. Before I move on to the next one, Dr. Johnson, I just want to go back to slide 24.

Now, we talked about developing the transdermal patch in connection with a base.

A. Right.

Q. Now, would the undue experimentation and unpredictability that you described for conducting the solubility testing, stability testing, crystal purity testing, pH solubility testing and solvent testing in connection with the salt, would that be more or less or the same as you described in connection with the atomoxetine base?

A. It would probably be more difficult, because you first have to decide what salt that might work, so you would make multiple salts. So instead of maybe one box, you'd have two or three more because you'd probably go through some of that first process with maybe two or three different salts.

Q. And could a person of ordinary skill in the art predict as of January 11th, 1995 without conducting any tests whether a particular salt would be suitable for a transdermal patch?

A. No.

Q. And why not?

A. Because there's no evidence or literature or anything

that I'm aware of that would provide help or assistance to the use of atomoxetine hydrochloride salts, hydrochloride salts or other salts for a transdermal patch.

Q. Now, Dr. Johnson, in total -- well, your estimate, how long would it take -- how long would it take to make a transdermal patch from start to finish, whether using a base or -- let's assume you're using a base.

A. Probably more than two years.

Q. And if you were using a salt?

A. Two-plus years, maybe three.

Q. All right. Dr. Johnson, let's move on to another dosage form, suppositories.

Can you go to 26, please?

Dr. Johnson, does the '590 patent call out suppositories as a potential dosage form for administering atomoxetine?

A. Yes.

Q. And where in the patent does it say that?

A. It's in the '590 patent, column 2, lines 28 to 30.

Q. And that's DTX-1?

A. DTX-1, I believe.

Q. Well, for the record, it's DTX-1.

Back to the slide, please.

Dr. Johnson, what is a suppository?

A. It's a dosage form where the drug is inserted into a

hydrophilic or hydrophobic matrix which is placed in some sort of body cavity to release the drug.

Q. Before we go any further, though, back to, just on the transdermal patch, are you aware of -- does there exist today a transdermal patch that's used for treating ADHD?

A. Yes.

Q. Do you know what drug that is?

A. I think it's methylphenidate.

Q. Back to the suppository. You testified it was inserted typically rectally; right?

A. I don't recall. It typically would be, but I don't recall what I said.

Q. Well, how would you characterize the absorption of a drug through the rectum?

A. It's typically erratic.

Q. I'm sorry: Rectal mucosa.

A. It's highly erratic.

Q. I'm sorry, can you repeat that?

A. Absorption from the rectum from a suppository is typically erratic.

Q. Does it avoid first-pass effect?

A. Yes.

Q. I meant does the drug avoid first-pass effect.

A. Correct.

Q. Now, does the prior art describe a suppository

formulation comprising atomoxetine?

A. No.

Q. Does it describe a suppository formulation comprising a propylamine?

A. Yes.

Q. Is atomoxetine a propylamine?

A. Yes.

Q. Now, let's take a look up on slide 26, Dr. Johnson. You have there a Formulation 5. Do you see that?

A. Yes.

Q. And you also have I believe what's DTX-166, U. S. Patent number 5,281,624.

Did you evaluate that patent --

A. Yes.

Q. -- as part of your analysis?

A. Yes.

Q. In your evaluation of that patent, what did you find?

A. I found a suppository formulation which included a -- it appears to be a propylamine, which I would assume would be a base. However, they pass it through a screen, which doesn't make any sense. So I don't know how applicable this truly is.

Q. Well, let's just back up.

You're referring to Formulation 5 --

A. Yes.

Q. -- on slide 26?

But what is this formulation directed to?

A. A suppository.

Q. Now, do you have an opinion as to whether or not Formulation 5 would have made it possible for one of skill in the art as of January 11th, 1995 to make a suppository containing an effective amount of atomoxetine for treatment of ADHD and, if so, can you tell us what that opinion is?

A. It wouldn't help.

Q. And can you please explain to the Court why that is so?

A. Because we don't know the dose of atomoxetine that would be necessary.

Q. Well, what's wrong with the dose that's on formulation 5?

A. We have no knowledge of what the dose for atomoxetine in a suppository should be because we don't know the absorption rate, we don't know the dose.

Q. Now, the '624 patent, is it directed toward treating any particular disorder?

A. Not that I'm aware of. It may have been depression, but I don't remember.

Q. Is it directed to treating ADHD?

A. No.

Q. And in that formulation, atomoxetine is not described;

correct? Formulation 5?

A. It's not in the patent.

Q. In the '624 patent.

A. Correct.

Q. You mentioned that it's not clear whether or not it's a solid or base form. Why is that?

A. Because they list it as a base, and so I assume the base is what was used.

Q. But why would that make it confusing, if at all?

A. Because they're pushing the base through a screen, like a regular screen, and I don't -- you don't do that.

Q. Now, where do you see that in Formulation 5?

A. In the instructions.

Q. Could you just recite where that is?

A. It's right below the formula.

Q. Just read it.

A. "The active ingredient is passed through a No. 60 mesh U.S. sieve and suspended in the saturated fatty acid glycerides previously melted..."

Q. Now, in your view, do you typically pass a base through a sieve?

A. No.

Q. What is it that you normally would -- what would you pass through that?

A. You pass -- pass a powder.

THE COURT: Counsel, can we take a short break?

MR. PARKER: Yes, Your Honor.

THE COURT: Okay. Why don't we take about 15 minutes?

(Recess taken)

THE COURT: Be seated.

(The witness resumed the stand.)

MR. PARKER: Thank you, Your Honor.

BY MR. PARKER:

Q. Okay. Dr. Johnson, just staying on slide 26, okay? Are you with me?

A. Yes.

Q. Okay. Dr. Johnson, given the information that's contained in the '590 patent together with the information that's in Formulation 5 of the '624 patent, what experiments, if any, would one skilled in the art need to conduct in order to prepare a viable suppository formulation comprising an effective amount of atomoxetine for the treatment of ADHD?

A. He would have to go through similar steps trying to determine what ingredients, the active ingredient, what can I use, the stability, solubility, and screen these ingredients to arrive at some kind of preliminary formula. He'd then want to put this in -- refine it so it can be put in animals. I don't know if you want me to go through all

of the --

Q. No, no, we'll do that individually. But just to look at slide 27, slide 28, now, in these slides, are you illustrating how one of ordinary skill in the art would prepare a viable dosage form?

A. Yes.

Q. Okay, and in what context -- well, what do you mean by a viable dosage form in this context?

A. Suitable that you could do a human efficacy study to determine whether or not it would be efficacious.

Q. And in your review of claims 1 through 16 of the '590 patent, do you believe that's necessary?

A. Yes.

Q. Now, does the '590 patent provide any guidance with respect to selecting the appropriate atomoxetine form for making a suppository?

A. No.

Q. Does the '624 patent provide any guidance as to what form of atomoxetine should be used for preparing a suppository?

A. I don't believe so, no.

Q. Excuse me?

A. No.

Q. Now, let's first turn to I believe -- well, where would the person of the ordinary skill in the art start

first with the atomoxetine selection, where would he begin?
A. He would probably begin with the raw material and decide is he going to do a base or a salt of some type.
Q. Okay. Now, do we know whether or not the base is stable?
A. We don't know.
Q. Is there anything in the 624 -- well, strike that.
Now, just staying on slide 27 and just following along, I believe, with the -- you said the base. So is this over here in the portion of slide 27 where you have the base, analytical method, --
A. Yes.
Q. -- and going down? Okay. Now, could you just tell us in this particular selection process, you have three tests, stability, solubility, and -- I'm sorry, I can't read that. That is?
A. Partition coefficient.
Q. Partition coefficient.
So let's just stick with stability. Why would one of ordinary skill in the art conduct these tests, and how would they conduct them?
A. Disability tests -- the first thing you've got to make sure, in every one of these, you have to look at the raw material, choose a pure raw material and then look at the stability, whether in the mix of ingredients or excipients

that you think you might use in the formula.
Q. And how would they go about testing that?
A. They would mix the drug with the excipient and put it in different temperatures. You'd look at -- light, in this case, is not quite as important because the form is not usually in a situation where it's going to be affected by light, but we typically would look at light, oxidation, we'd do some things under nitrogen just to make sure that that doesn't make a difference.
Q. And suppositories, when administered, they melt?
A. Yes.
Q. And does that have an effect on as to why you would look at the stability of the active ingredient?
A. One of the -- one of the things we'd look at.
Q. All right. Now, with respect to solubility, on slide 27, coming off of the -- where it says base analytical method, why would one of ordinary skill want to consider solubility, and how would they go about assessing solubility?
A. I'd want to know what ingredients it's soluble in, whether or not I would use a solvent in the system to help carry it out of the suppository, a penetration enhancer to determine whether or not I would need that to get improved absorption.
Q. And again, we're just looking at the -- determining

whether or not the atomoxetine base would be suitable at this point; correct?

A. Correct.

Q. And how would they go about looking at solubility?

A. In this case, you usually -- you'd actually just put the base in different solvents and determine how much of the drug went in solution.

Q. Now, looking at the partition coefficient testing, why would someone of ordinary skill in the art have to look at that, and how would they go about doing it?

A. You'd want to get an idea of what it is. That tells you sort of how hydrophobic the drug is, the base drug is, and if you have a very hydrophobic vehicle, I don't think you'd use that because it would stay -- it would migrate out of the vehicle. So you'd want to know some relationship between the hydrophobicity of the vehicles you might use and the drug, and if you want to determine the hydrophobicity of the drug, you can put it in an organic solvent, like octanol, and then you can shake it up with octanol and water and then it will separate and then we can measure how much resides in each phase. So it gives you a measure, rough measure of how hydrophobic it is.

Q. Okay. Now, you mentioned the word "hydrophobicity." Just, what does that mean?

A. That means it's oil-loving instead of water-loving.

Q. Now, turning to the other side of your slide here, slide 27, Dr. Johnson, you also have a portion where you have a selection of a -- a process for selecting an appropriate salt. Do you see that?

A. Yes.

Q. Now, are there any tests that are in the -- when dealing with the salt, are there any tests that are being carried out here in selecting a form of atomoxetine stage, are there any tests in this portion of your schematic that are not in the base, dealing with the base?

A. Yeah. We would have a crystal here, so we'd want to know what the crystal purity is, and we wouldn't know -- at this point, we don't know what salt we might try. It's my understanding that the hydrochloric may be irritating, so you might not want to use that, so you might look at some other salts.

Q. Now, with respect to the selecting the form of atomoxetine both from the perspective of the selecting the -- analyzing the base and selecting the salt form, you have -- shown on this slide, you have arrows, and you have yes and noes. What were you trying to convey in this aspect of the development process?

A. As you go through these diamond steps, you find properties that you didn't anticipate, and if you don't think that's acceptable, then you maybe have to regroup and

go back and do it over.
Q. Now, when analyzing the base, in carrying out these series of tests that you indicate on slide 27, stability, solubility, and partition coefficient, approximately how long would it take one of ordinary skill in the art to complete those tests?
A. For the base, probably three to six months. The raw material probably would take longer because you don't know -- at this point, you have no idea which salts you would want to try to use.
Q. Okay. So my next question was, then, how long -- with respect to the -- in selecting a salt in connection with selecting the form of atomoxetine, would that be longer than it would be for the base?
A. Yes.
Q. And how much longer?
A. I think probably at least three months.
Q. Now, based on what you've seen in the prior art, including the '624 patent, as well as the '590 patent, could a person of ordinary skill in the art predict what salt form would be appropriate for a use in a suppository without conducting any testing?
A. No.
Q. And could the person of ordinary skill in the art as of January 11th, 1995, would they be able to ascertain

whether or not atomoxetine freebase would be suitable for a suppository without conducting any testing?

A. No.

Q. Now, once you've evaluated the base and the salt for atomoxetine, what is the next step one skilled in the art would have to conduct?

A. We would put these ingredients together in some sort of formulation and compatibility test with the other ingredients we would select.

Q. So is this what you're referring to, your preliminary formulation --

A. Right.

Q. -- and excipient selection, --

A. Correct.

Q. -- which is on your slide 27?

A. Correct.

Q. Now, what, if any -- given the prior art as you had read and evaluated it, what if any preliminary assessments would one of ordinary skill in the art have to conduct in dealing with the step here, preliminary formulation and excipient selection?

A. We'd put the materials together in a suppository form and then we would look at the impact of melting point, we'd look at in vivo dissolution to make sure that the drug was coming out of the dosage form, and we'd do stability

studies.

Q. And for both the base and salt, you have MP differences, in vivo dissolution, and you have stability; is that correct?

A. Right.

Q. Now, can you just -- well, why is looking at the melt, MP -- MP stands for melting point?

A. Yes.

Q. Why is it important to assess the melting point differences? Why make that assessment?

A. Because the dosage form really has to melt to release the drug.

Q. Now, would the excipients in the suppository have an impact at all on melting point of the suppository?

A. Yes.

Q. It could increase it or decrease it, the melting point?

A. Right. Yes.

Q. Why does one skilled the art with respect to both the base and salt need to conduct in vitro dissolution testings?

A. Because what you're doing is trying to get a method of assessing whether or not the drug is released in the dosage form.

Q. Now, with respect to a suppository, why is release important?

A. It has to be released so that it can pass through the rectal mucosa into the tissues and into the bloodstream.
Q. Now, with respect to -- now, with a suppository, the drug is released as it's melting? Is that how it works?
A. Once it's melted, it kind of coats the mucosa and then it releases from there.
Q. And why is stability important when formulating -- why would one skilled in the art need to assess stability when you're looking at the preliminary formulation and excipient selection stage?
A. Because it must be compatible with the ingredients you're selecting so that it will remain stable.
Q. And how do you look at stability? How does one of ordinary skill make that assessment?
A. In this case, you would analyze for intact drug.
Q. Now, again, as we go through the process both from -- well, with respect to the preliminary formulation and excipient selection process as you've laid it out in slide 27, you've made some notations there with the arrows. Are you trying to convey that it's an iterative process?
A. Yes.
Q. Can you explain why it would be an iterative process?
A. Because before you do the work, you can't predict what's going to happen.
Q. Now, could one -- could a person of ordinary skill in

the art predict as of January 11, 1995, without conducting any test what excipients would yield a suitable preliminary suppository formulation allowing you to proceed to the next step?

A. No.

Q. Now, based on your experience, Dr. Johnson, with respect to the base, how long would this particular aspect of the process take? I'm referring to the preliminary formulation and excipient selection stage.

A. That would probably take another three months. To get to refined formulation, we're talking six to nine months.

Q. I'm sorry. What was that?

A. We're talking six to nine months, roughly.

Q. And with respect to the salt, would that be longer, shorter?

A. I think it would be maybe S three months longer.

Q. And why would that be longer for the salt?

A. We really have to pick the salt. It takes time to make the salt, characterize the salt, analyze the salt. So you lose maybe three months in the front end making these salts and characterizing them.

Q. Okay. Now, let's just go to the refined formulation step that you've laid out in slide 27.

Now, for both the base and the salt, I believe the tests would be similar?

A. Yes.
Q. They would include -- tell us what they would include.
A. We would certainly look at stability and -- of various types, and we would look at in vitro dissolution.
Q. Okay. So for the base, why would one skilled in the art look to stability, look at stability? How would they go about assessing it?
A. You would really look, make sure that the drug stayed intact in the time you had to evaluate it. In this case, you don't have a lot of time because you're trying to move it along, get to the next step, but you could also rely on the prior stability with these excipients. At this point, you're refining it to the point where you can actually administer, make a suppository and administer it to a dog. The first one would be ranges of -- ranges of drug in these various systems, but not necessarily shaped in the suppository. When we go down here, we're starting to actually make suppositories with the drug that we can give to a dog in this case.
Q. Now, with in vitro dissolution, why would one of ordinary skill in the art want to assess that, and how would they go about doing it?
A. We would want to continue to evaluate the rate at which it releases the drug.
Q. And just quickly, with respect to the salt selection,

as far as the how and the why with respect to what one of ordinary skill would do, would your testimony be the same with respect to the base as it would be for the salt form?

A. Yes.

Q. Okay. Now, let's just move down to the -- what is the next step? Once you've refined the formulation, what would one of ordinary skill in the art do if they were going to pursue the base as the potential active ingredient?

A. We'd like to determine whether or not it's released appropriately in at least some kind of in vitro -- in vivo model, like a dog.

Q. And can you explain the type of studies that would be undertaken?

A. You'd do a blood level study on the dog and look at the rate of release and extent of release of the drug from the suppository.

Q. Now, on your slide, you also mention bioavailability. What does that mean?

A. It means we're looking at the rate of release, extent of release, and the blood levels.

Q. Now, you also have the same testing also for the salt form as well?

A. Right.

Q. So your description with respect to the carrying out those tests for the base, would that be also the same for

the salt form?
A. Yes.
Q. And you have a circular arrow next to that step, the animal PK study step. What is that intended to convey?
A. That's to determine whether or not we would have to go back and rerun the tests and go back and refine the formula again.
Q. Now, Dr. Johnson, now, are these, any of these steps -- let's just talk here, with the base, going to the selecting, is selecting the form of atomoxetine to determine whether or not it's suitable, is that a routine step?
A. No.
Q. Why would you not consider that to be routine?
A. Because it requires a high level of training, skill, and evaluation ability.
Q. And what about selecting the preliminary formulation and excipient selection phase: Are the underlying tests for that, would you consider those to be routine?
A. No.
Q. And why not?
A. Because they -- they just are not. There are certain steps that may be routine, for example, weighing, pouring, mixing, a lot of those steps are not necessarily -- you can say they're routine, but you have to do them in the context of what your goal is, and that's where it takes a certain

intellectual content or ability or -- to perform and get the right answers.

Q. And to your knowledge, with respect to animal PK studies, were those -- do you consider those to be routine?

A. No.

Q. And just explain why.

A. You have to relate this blood level to the release of the drug, make a decision whether or not that's adequate, inadequate; is it irritating. So it's not simple.

Q. After refining the formulation, what is the next step one skilled in the art would carry out?

A. We do the dog study, and we try to pick whether or not either one of these might be satisfactory.

Q. When you do the dog study, are you talking about the animal PK study?

A. Yes.

Q. All right. After that is all done, what is the next study, the next step?

A. We take that evidence or information we got, try to pick whether or not we thought the base is more promising or the -- or it makes -- which does it make sense to do, do you want to do the base or do you want to do the salt, for example, is one more stable than the other, does one release more completely than the other, does one have more or less irritation than another? It's a matter of judgment which

one you take, because you really at this point don't want to carry too many things through to the next step.

Q. Okay. Now we're going -- what would be the next step once you've done that?

A. We refine the dosage forms used, the dosage forms and the raw material or active constituent that we used in the dog study, and we'd put that in formulation suitable for dosing people.

Q. And you have a whole series of tests. Can you just identify what those are?

A. You'd start running some additional tests, which could have an effect on physical form, like you'd freeze it, thaw it three or four or five times. You'd look at the stability of the drug, you'd look at appearance; in other words, does it get misshapen so that it doesn't hold its shape. You'd run dissolution. You'd look at penetration studies to determine whether or not is it getting softer with time as we -- as we -- in other words, as it ages, does the dose -- does the wax matrix retain its strength. It's pretty important that it's homogenous, because if you pour these and if it separates too fast when you're making the suppository, you're not going to get a suppository which is homogeneous.

Q. Let me back up there. What happens with -- just sticking with the homogeneity of the suppository, the active

ingredient mix in the suppository, when administering a suppository, why is it important that the drug be homogeneously mixed throughout?

A. So that it releases consistently.

Q. What is the next that we have over there?

A. We have hydrophobicity. We want to get more information on whether or not it's moisture-sensitive. It's just really a -- it's really another stability test that we do. But I'm just saying, the difference is, we were expanding some of the testing we're doing because it's now going into people. We want to make it safe, consistent.

Q. Now, you have -- again, without -- if you would just expand a little bit, we haven't seen freeze/thaw. How would one go about conducting a freeze/thaw test?

A. You actually take the suppository, you put it in -- you can put it in a bottle, you can put it in anything, and you put it in the freezer, and then you bring it out of the freezer -- put it in the freezer for 24 hours, take it out for 24, back and forth. You usually do four cycles.

Q. Again, what is the purpose of doing that? Why one of ordinary skill in the art want to assess that?

A. You want to make sure that the physical form of the waxes, the things that you have in that system don't change, because, if they change, they probably will change the release rate.

Q. Okay. Now, would you consider this -- as you have laid it out in slide 28, the various testing involved with refining the formula for the suppository, would you consider that aspect of the process routine?

A. No.

Q. And why would you not consider it routine?

A. Because it involves a lot of decisions along the way. I laid it out in a way I thought that I would expect a formulator to follow this path.

Q. Now, again, you have the arrows, and you have the yeses and the noes. Are you trying to convey there that it's -- well, why don't you tell us, what are you trying to convey here with respect to refining the formula for the human studies?

A. I want to make sure that I've refined it sufficiently and it's going to be consistent so that when I can give it to humans, I'm going to get consistent results, consistent data, I can understand the relationship of the release of the suppository to the blood level and excretion and have a system which is suitable to determine the efficacy.

Q. Okay. But now, again, just -- is this an iterative process in your view?

A. You hope it isn't at this point, but it would be, yes, depending on whether or not the results are satisfactory.

Q. All right. Now, let's just go to the next step. Once

you've refined the formula for human studies, what do you do next? What would one of ordinary skill -- where would you go in that direction? What would you do next?

A. We prepare supplies and do a human efficacy study.

Q. Well, hold on. You have human PK studies that are listed there as well.

A. Yes, I thought we did those, but --

Q. I don't -- would you just -- I don't believe we did, but could you just describe what would be involved or -- why would you need to conduct the PK studies, human PK studies?

A. Because we really need to look at the release of the drug from the suppository and how it relates to blood levels because we don't know the dose of atomoxetine when it's given by a suppository.

Q. Now, you have an arrow that's indicated there, a circular arrow. What is that intended to convey?

A. It could be iterative.

Q. Now, what's the next step after that, human PK studies?

A. After that, we'll make a decision on whether it's active enough or effective by conducting human efficacy studies.

Q. And does the patent require that the suppository be effective in treating ADHD?

A. Correct.

Q. And is that one reason among others that you would conduct the efficacy studies?

A. Yes, we need that as well to determine the dose. We don't know the dose.

Q. Now, how long would it take -- roughly, about how long would it take to carry out, to complete the step here about refining the formula before you get to the human studies?

A. Probably about two to three months.

One of the problems here is the stability studies are -- you've got -- you can't -- it's very difficult to accelerate a suppository because it melts. So you can accelerate stability, but these physical forms, like freeze/thaw or durometer, some of these physical tests, you can't really accelerate those. You can accelerate chemical degradation, but it's hard to accelerate other physical testing here. So it would be more than a month. It would probably be two to three months.

Q. Now, any -- do you have any idea with respect to the human PK studies how long those tests would take to carry out?

A. Three to six months.

Q. And any idea about the human efficacy studies?

A. I think they would be six months-plus, six months or more.

THE COURT: You've been giving testimony where

you've talking about a time period, and, of course, you've used the phrase the undue amount of --

THE WITNESS: Right.

THE COURT: -- testing.

When does it become undue?

THE WITNESS: In my mind, it -- what I try to do is look at all these Wands factors and describe those versus the amount of work necessary to do any of these tests, and the lack of data and information in the patent as well as the prior art is what I'm trying to base whether or not it's undue or not.

THE COURT: Well, the point is, there would be a certain amount of time necessary under any circumstance; correct?

THE WITNESS: Correct. Correct.

THE COURT: Well, when does it become -- what tips it into the undue category?

THE WITNESS: In my mind, if you can do it -- if -- if a person skilled in the art, when I look at these, like a year or less. If I can do it all in a year or less, that's probably not undue. If the information is also in the literature, which helps, for example, making a tablet, capsule, tablet. These other, there's almost no information, and we're well over one to two years on almost every one.

THE COURT: So what causes it to be undue is the amount of time?

THE WITNESS: No, it's actually the amount of work. It's uncertainty, predictability, unpredictability, amount of work, time.

THE COURT: So the time is merely one factor?

THE WITNESS: It's one factor.

THE COURT: In any event, it's subjective.

THE WITNESS: It is subjective.

THE COURT: And why did you just say one year? What --

THE WITNESS: Well, that -- that was kind of a -- I laid out the development of all these things and tried to group them, I could -- I could group the oral, solid, tablet, capsule, fast-disintegrating tablet for oral use, I could kind of group those all together in a matter of time. The rest of them all grouped, longer. And it ends up -- there's more uncertainty and unpredictability in those other forms. The capsules, that's a dry system. There's no liquid. It's unlikely to have a stability problem. That's a big issue. The need of not having to make a new salt is a big deal. That's expensive. I've been involved in several situations where they didn't make the right salt, it wasn't the right purity, and you delay things for three -- three months to a year, and you repeat all that work.

What else?

It's issues like that. That's how I kind of think they're different.

THE COURT: Okay.

BY MR. PARKER:

Q. Now, Dr. Johnson, just in your opinion, in your experiences, when developing a suppository, what are some of the challenges that one of ordinary skill would encounter as they develop this product -- I'm sorry, this viable dosage form?

A. Probably the biggest one is, we don't know the dose, and we don't know the rate of absorption or the extent of absorption from the rectum, and the variability, irritation, unpredictability is a big issue. You don't know how many patients you're going to need to do because you can't predict the release rate.

Q. Now, during your deposition, you were asked whether or not a pharmacist can simply just take a tablet, grind it up, let's assume the tablet has 50 milligrams of the effective amount, which to effectively treat ADHD that a pharmacist could just simply grind that tablet up and throw it in a suppository. Do you have any idea or any view as to whether that would be a viable dosage form in your view?

A. I don't believe it's viable.

Q. It would not be viable?

A. No.
Q. Would the physician or the pharmacist have any basis to believe that it would actually work to treat ADHD in your view?
A. He shouldn't have. He doesn't know the dose.
THE COURT: He doesn't what?
THE WITNESS: Know the dose. That route of administration, we don't know what the dose is.
Q. I mean, is that a correlation between what a dose is in a tablet and what you can actually put into a suppository?
A. In this case it's pretty uncertain because you have two types of metabolizers, and the rectal route, the drug should not be metabolized that way. So it's not predictable.
Q. Right. You referred to the absorption through the rectal mucosa as erratic?
A. Yes.
Q. Dr. Johnson, with respect to the slides 27 and 28 that we looked at for the suppository, were those slides prepared based on your instruction and direction?
A. Yes.
Q. And they were prepared today for your testimony?
A. Yes.
Q. And in your opinion, do they reflect how one of

ordinary skill in the art would go about developing a dosage, a suppository?

A. Yes.

Q. Dr. Johnson, just moving along, based on your consideration of the Wands factors that you referenced last week and you referenced this morning, have you formed an opinion as to whether or not as of January 11th, 1995, undue experimentation would have been required by a person of ordinary skill in the art to prepare a suppository comprising an effective amount of atomoxetine in some form to treat ADHD?

A. I think it would take undue experimentation.

Q. Okay. So let's take -- let's move on to a different dosage form.

Suspensions. What is a suspension?

A. That's where you have a suspended solid in a liquid.

Q. Now, are suspensions called out in the '590 patent?

A. I believe so.

MR. PARKER: Slide six.

A. Yes.

Q. And where in the patent is it identified?

A. It's "usual oral pharmaceutical forms, such as tablets, capsules, suspensions and the like."

Q. Does the '590 patent provide a working example of a suspension?

A. No.

MR. PARKER: Slide 29.

Q. Now, in your review of the prior art, Dr. Johnson, did you come across any references that disclosed a suspension that contained a propylamine?

A. Yes.

Q. Now, atomoxetine is a propylamine, is it not?

A. Correct.

Q. But did that reference specifically deal with atomoxetine?

A. No.

Q. And any idea as to what indication the drug that's described in the '624 patent, which is DTX-166, what the condition was that was being treated?

A. I don't know. I think these were all depression.

Q. You believe it's depression? Was it directed to ADHD?

A. No.

Q. Now, was there -- on your slide, at 29 you have Formulation 6. Do you see that?

A. Correct.

Q. Now, did you consider that formulation?

A. Yes.

Q. And why did you consider that particular formulation as a part of your analysis?

A. Because it was a propylamine. It was a suspension,

purported suspension, but when you read the formula and the ingredients and the method of manufacture, I don't believe you could use it as an example. It's not really relevant.

Q. All right. Do you believe it's helpful or unhelpful, the formulation?

A. It's not helpful because it looks like they're using an amine. An amine would be an oil. They're passing it through a sieve, which reduces credibility because you wouldn't pass the oil through a sieve.

Q. Well, then, Dr. Johnson, after your evaluation of the '624 patent, which is DTX-166, given that, and given the information in the '590 patent, did you -- well, what experiments, if any, would a person of skill in the art need to conduct in order to prepare a viable suspension formulation?

A. This is another chart with --

Q. This is a chart that was prepared pursuant to your direction and supervision?

A. Right. Right.

Q. For your testimony today?

A. Yes.

Q. Okay. So you've looked at at least -- you've identified the '624 patent which had a formulation in there that you evaluated, and you also looked at the '590 patent. So now does this -- what does this slide illustrate now with

respect to your -- given your evaluation of those materials?
A. To make a suspension, you're going to need an insoluble salt. I don't believe it's practical to use the base. So if we want to make a suspension, we'd want to choose an insoluble salt.
Q. And why would it not be practical to use the base?
A. It's an oil.
Q. And does the '624, the '590 patent identify any particular salt form that would be suitable for a suspension?
A. No.
Q. At least with respect to atomoxetine.
A. Correct.
Q. Okay. So, now, does the '590 patent provide any guidance at all in terms of what salt one would want -- one could use for a suspension?
A. No.
Q. All right. And what is a -- we've talked about viable dosage forms. Just, what do you mean by viable suspension?
A. It's a suspension that would be safe, effective, and we could dose it to people.
Q. So now how does one skilled in the art as of January 11th, 1995, how does he or she go about selecting an appropriate form of atomoxetine for a viable suspension?
A. We really need to pick a raw material, which is in a

soluble salt, and then we need to test one or more of these with regard to stability, particle size, crystal purity, dissolution, and solubility to determine whether or not it might be appropriate.

Q. All right. Now, just, I know you have four -- five different tests, stability, particle size, crystal purity, dissolution, and solubility pH on slide 30. Again, so what are we looking -- in carrying out the stability test, what is one skilled in the art looking at? What are they looking for?

A. Say that again?

Q. With respect to the stability test that you have on slide 30, what is one in the ordinary skill in the art looking at? Why are they conducting this test?

A. We're conducting it because, at the end of the day, you have to have a stable, effective suspension of product to dose people.

Q. And you mentioned stability testing before. Generally, what does it entail?

A. In this case, it would entail putting -- putting the insoluble salt in water, suspending it and looking -- we would probably do multiple pHs, and we would look at dissolution from these different pHs and also the drug itself, does it retain its potency.

Q. Now, is particle size an important aspect of a

suspension?
A. Yes. Ultimately, if it's too big, it will settle; if it's too small, it might dissolve too fast when you're feeding, putting it in your mouth. So you're going to have to adjust particle size so it will stay in suspension but you could still use it as an oral dosage form to get adequate absorption.
Q. Okay. So how does one skilled in the art go about adjusting the particle size?
A. Well, you produce it in different particle size. You might even mill it. If you make a big one, you might mill it, although you would really try to crystallize it in a controlled fashion.
Q. Now, you also mentioned crystal purity. Why is that important in connection with developing a suspension?
A. Because at the end of the day, you have to administer pure drugs. You can't -- you can't have decomposition in the drug.
Q. All right. Now, with respect to dissolution, why is that an important assessment to make?
A. Because initially, it's got to pass -- it's got to be -- dissolve slow enough to get through the mouth and fast enough so it can be absorbed.
Q. Absorbed where?
A. In -- through the -- goes into the stomach, into the

intestine, and then it is absorbed.

Q. And with respect to solubility, pH, how does -- why is that an important -- why is that an assessment that needs to be made?

A. In this case, we were going to probably adjust pH to control solubility to some extent.

Q. Now, when you're going about selecting the form of atomoxetine, do you have a view as to whether or not it's an iterative process?

A. It typically is.

Q. And could you just explain, why is that? Why would that be?

A. Because you're going to have to use multiple-size particles. You're going to have to -- you have a lot of parameters, things going on at the same time. Just the physical attributes of just particle settling, it's got to settle slow enough so that you can actually just shake it, pour out five mls or whatever the quantity is and dose that and not have it settle so fast you can't get the same amount every time you pour it out.

Q. And just based on your experience -- well, first of all, could one of ordinary skill in the art predict without conducting any tests what salt form of atomoxetine would be appropriate for a suspension?

A. No.

Q. You'd have to conduct the tests?
A. Well, he'd go to the literature, he'd get leads, he'd make the compounds, and then he'd do the tests.
Q. And I know we've been talking about in terms of how much time it takes to carry out certain aspects of these development phases. Well, first of all, is selecting the form of atomoxetine, is that a routine process? Would that be a routine process for one of ordinary skill in the art as of January 11th, 1995?
A. No.
Q. And why is that?
A. It requires a pretty -- pretty good level of skill, assessment of the literature, chemistry, and trying to determine which might be the most appropriate salts.
Q. And approximately how long would it take for one of ordinary skill to carry out these tests that you've laid out on slide 30 in connection with selecting the form of atomoxetine?
A. It would probably take at least three months to get the raw material and another three months to get to the point where you're evaluating preliminary formulations.
Q. Well, let's just focus on just, you've got the raw material and you're carrying out the tests. How long would that take, approximately?
A. Two, three months.

Q. Okay. Now, once you've actually selected -- you found the lead and you selected the form of atomoxetine you want to go with, what's the next step?

A. We'd make the preliminary formulation excipient selection, and then we'd do -- we'd make this in a suspension, we'd do the stability tests with the excipients that we thought were the most appropriate.

Q. And then you listed a series of tests there. Can you just read -- could you just tell us what those test are on slide 31?

A. Yes. We'd do stability testing. We'd look at the suspendability, caking, degradation. We'd look at resuspendability, uniformity, dissolution, viscosity, taste, microbial growth.

Q. Now, when you talk about stability -- and let's talk a little bit about viscosity. Why is viscosity important?

A. That helps to determine how long the particle size and the particle mass, how long it will stay suspended.

Q. And what type of testing is done to make that assessment?

A. You can do various things. We use a viscometer for viscosity.

Q. Now, you have taste. Is taste a factor in developing a suspension?

A. Yes. That's the reason we're making a suspension,

because taste is -- of a liquid, it's my understanding, would probably be very bitter.

Q. What would be very bitter?

A. The taste of atomoxetine.

Q. But why is the bitterness a factor in developing a suspension?

A. People won't take the dosage form if you don't -- if it's not palatable.

Q. You can force them to take it; right?

A. I don't think you'd want to do that to your kid.

Q. Well, let me ask you, you understand the ADHD is treated over a long period of time; is that your understanding about ADHD?

A. Correct. You have to take this four to six weeks to see its efficacy, and it's a product that you anticipate that you'd be taking for years, and so it's just not reasonable to make something that's not palatable.

Q. Would you consider a viable suspension one that's palatable to patients?

A. Yes.

Q. Now, so how does one go about -- now, when you're dealing with bitter taste, is taste masking a phrase that comes to mind?

A. Yes.

Q. What is involved with taste masking?

A. You'll do a variety of things. You'll change the sweetness of the product, you can add sweeteners, you can add flavors. You can do different -- different things like that.

Q. Is there anything out there in the literature that would tell you which particular ingredients would sufficiently or successfully mask the bitter taste of atomoxetine?

A. Well, there's a lot of literature to help you choose which ingredients will flavor bitter things better than others. So you would use literature, you'd pick things like and then you'd try it, see if it works.

Q. And as of now, sitting here today, do you know of any particular compound that might be able to mask the bitter taste of atomoxetine? Or you'd have to carry out the tests?

A. In any case, you have to carry out the tests because you've got to confirm you were right.

Q. Now, you mentioned microbial growth. What does that mean? Why is that a factor?

A. Because you've got -- it's a liquid system. You likely will have microbial growth. It's easy to get contaminated.

Q. Now, just looking at resuspendability and uniformity, what do you mean by that?

A. That's so when it's dosed, you get the same amount of

drug per dose, and if it's not resuspendable, you won't.
Q. And why is that important in developing a suspension?
A. Because any time you dose somebody, you're trying to get a certain amount of medicament to fulfill that dose request.
Q. Now, the resuspendability and uniformity of any suspension, would that have an effect -- is that affected by the excipients in the suspension itself?
A. Yes.
Q. And stability, you mentioned degradation, caking, and sedimentation. What do you mean by caking?
A. That's when you hold the bottle up and the bottom -- the drug's all caked and the other excipients are caked on the bottom, and they won't resuspend.
Q. And sedimentation; what do you mean by that?
A. Well, most of the things we have in there are insoluble, and that's where they settle.
Q. And you also mentioned degradation, and how is that assessed? How would that be assessed by one of ordinary skill in January of 1995?
A. We would assay it for the intact compound and the degradation product.
Q. All right. So in carrying out all these various tests to obtain a preliminary formulation and excipient selection, do you have a sense of how long this process might take?

A. Probably at least three months plus.
Q. Again, from the perspective of one skilled in the art, would you consider this process here of identifying and selecting a preliminary formulation and excipient selection, would that be an -- would you consider that to be routine?
A. No.
Q. And just why is that?
A. Because there's a lot of factors here to consider and blend together to arrive at a decision which is an effective decision and both select a dosage form which is likely to be worthwhile to be carried forward.
Q. Now, what's next after you've carried out the preliminary formulation and excipient selection step? You've finished that. What's the next step?
A. We are on suspensions because you really at this point are not completely sure of the solution rate. We always did a rat toxicity maximum tolerated dose test. It was not a long-term test. It's a test, maybe about a month.
Q. Now, -- well, let me back up quickly.
Now, just on the selecting the form of the atomoxetine, would you consider that to be an iterative process as well?
A. Yes.
Q. And again, with respect to this aspect of the development process, the preliminary formulation and

excipient selection, you have arrows, you have other indications there. What was it you were intending to convey with that process?

A. That if any one of these fails, you have to go back and start, make some modifications.

Q. All right. So now once you've done the -- you've finished the preliminary formulation and excipient selection step, what's next? What would one of ordinary skill in the art, where would they go next?

A. We'd go to the animal tox test and then go to the animal PK test.

Q. And what would be the objective of conducting those tests? Why conduct them?

A. To try to assess the approximate rate that the drug might be -- drug from this solid, insoluble drug material is going to be released.

Q. And any sense of how long that would take?

A. Oh, about three months.

Q. Okay. Now, once you've conducted your animal PK studies, you've collected your data, what's the next step that one of ordinary skill in the art would do?

A. We'd refine the dosing suitable for and concentrations suitable for doing a human PK study.

Q. All right. Now, you've listed a series of tests under "Refine Formulation": Stability, resuspendability and

uniformity, dissolution -- and I'm speaking of slide 32 -- viscosity, taste, and microbial growth. With respect to what one of ordinary skill in the art would do in connection with those tests, is that the same as you described it in the previous slide, in 31?

A. Correct. Correct.

Q. And is this aspect of your refining formulation, is that also an iterative process?

A. Yes.

Q. And why do you call it an iterative process?

A. Because unless you're extremely lucky, you won't always hit every mark.

Q. Now, you used the words "extremely lucky." Does that happen often?

A. Yeah.

Q. It does?

A. No, not being extremely lucky.

(Laughter)

A. It's not -- you're usually not lucky enough to always be correct.

Q. Okay. Now, what happens now? You refine the formulation. Where does it go next?

A. We do the human PK study to try to assess the rate of drug release and the rate of absorption and the blood levels because now we have an insoluble salt, and it's really

important that you make sure the drug is fully released.
Q. And what are some of the things -- just to be clear, what are some of the things -- when you carry out the human PK studies, what are some of the -- what is it that you're looking for? What type of data are you generating?
A. We're looking at the in vivo or in-the-body release rate of the drug. We'd be looking at the blood levels that it gave and the --
Q. Now, would that be an iterative process as well?
A. It could very well likely be if we're not getting -- if an extent of absorption is not suitable, you'd probably have to repeat it.
Q. All right. Now, you've done your human PK studies. What's next?
A. We'd have to look at the human efficacy studies to confirm that it complies with the patent.
Q. And is that because this claim 1 -- does claim 1 require that it be effective?
A. Correct.
Q. Now, again, could one of ordinary skill in the art not get from the -- can they refine the formulation without conducting any testing?
Let me back up.
Is there any way that one of ordinary skill in the art could predict how to refine the formulation without

doing any experiments?
A. I don't believe you could predict it. In most of -- in some of these cases, you can skip some tests if you have prior data or prior art; but in this case, we don't have any.
Q. And do you have a sense of how long it would take to carry out the human PK studies?
A. Three to six months.
Q. And the human efficacy studies?
A. Five or six months plus.
Q. And what about the refining formulation?
A. About three months.
Q. Now, in developing a suspension, in your experiences, Dr. Johnson, what are some of the challenges one of ordinary skill in the art would encounter?
A. Picking the right salt.
Q. That would be a challenge?
A. Yes.
Q. And is there anything else? Controlling release, is that a challenge?
A. It's a problem to estimate the release that's appropriate, in other words, it's not too fast, not too slow, so that you get roughly equivalent release of the drug as you would with let's say a capsule of soluble material.
Q. What about getting the release in the gut; is there a

challenge there when you're dealing with a suspension versus a tablet?

A. Correct.

Q. What is that?

A. Because we've made an insoluble salt, so it's not soluble, so it's going to have to dissolve.

Q. And again, just the challenge with respect to the absorption in the gut and the suspension, what is it -- I mean, there's a dynamic there in terms of you want it to happen in the gut, so what is the challenge that --

A. It's got to be in solution.

Q. Now, based on your consideration of the Wands factors, have you formed an opinion as to whether as of January 11th, 1995, undue experimentation would have been required by a person of ordinary skill in the art to prepare a suspension having an effective amount of atomoxetine in any form to treat ADHD?

A. Yes.

Q. And what is that opinion?

A. I think it would take undue experimentation.

Q. Now, Dr. Johnson, let me just make a point here.

With respect to slides 31 and 32, in making this presentation in this discussion, are you suggesting that the '590 patent have included all the data that's generated in connection with slide 31 and slide 32? Is that your view,

that the patent should contain all that information?
A. It should contain some information. For example, if they select a salt, it would be a great help. And possible concentrations. Some information like that.
Q. The fact it doesn't have a working example of the specification; does that have a -- does that play a -- is that a factor in terms of carrying out the study --
A. Yeah.
Q. -- as you've laid out in slides 31 and 32?
A. Yes.
Q. And what impact does that have?
A. There's no working examples.
Q. Right. The fact that there are no working examples; what does that -- as far as one of ordinary skill is concerned, what does that mean? What do they have to do?
A. That favors undue experimentation.
Q. And with respect to the experiments you've laid out in 31 and 32, there's no working examples, so why do those experiments still have to be carried out?
A. Yes. You said why do they have to be carried out?
Q. Yes.
A. Because there are no working examples and you have no information.
MR. PARKER: Your Honor, I'm going to go on to another dosage form. I don't know whether this would be a

good time for lunch. I'm more than prepared to go forward.

THE COURT: Would everyone like to break for lunch at this time?

Speak up, cowards. You can talk.

(Laughter)

THE COURT: All right. We'll break for lunch. We'll take an hour. Come back about 1:30.

All right. You may step down, sir.

THE WITNESS: Thank you.

(Luncheon recess taken)

A F T E R N O O N S E S S I O N

THE COURT: Be seated.

(The witness resumed the stand.)

THE COURT: Okay.

MR. PARKER: Thank you, Your Honor.

THE COURT: Proceed.

MR. PARKER: Thank you, Your Honor.

BY MR. PARKER:

Q. Dr. Johnson, are you ready? Are you ready?

A. Pardon me? Am I ready? Yes.

Q. Dr. Johnson, just on the, if you look to the slide, I just want to just go back before we went to injectable solutions.

We were talking about the '624 patent, and it shows you Formulation 6. And within that Formulation 6, it says -- it identifies flavors. Do you see that?

A. Right.

Q. Now, with that disclosure, is that sufficient for -- is that sufficient information for one of ordinary skill in the art to know how to go about taste-masking the bitter taste of atomoxetine?

A. No.

Q. And why is that?

A. It doesn't describe the flavor.

Q. Excuse me?

A. It doesn't describe what flavors you use, nor does this compound atomoxetine.

Q. Dr. Johnson, let's move on to what's referred to as injectable solutions.

MR. PARKER: Can we have slide 6, please?

Q. Now, injectable solutions, are they called out in the '590 patent?

A. Yes.

Q. Can you just tell us where in the patent that's located?

A. It's line 20 -- 28 or 9 of column 2.

Q. I'm sorry, did you say column 2, lines 20 --

A. -- 8 to 30.

Q. Twenty-eight to 30. Thank you.

Does the '590 patent disclose any working examples of an injectable solution?

A. No.

Q. What is an injectable solution?

A. A solution which the drug is in solution and you inject it either IM, subcutaneous, you might drip it in, or it might be a bolus injection.

Q. Now, does -- at that -- using that form of administration, does the active ingredient undergo any first-pass metabolism?

A. No.

Q. Now, in your evaluation of the state of the art, did you come across any patents or published literature describing or dealing with atomoxetine in connection with an injectable solution?

A. Yes.

Q. And which patent did -- well, where did that come from? What information are you referring to?

A. Well, one of these mentions injectable solution in the patent, DTX-3, '081.

Q. Okay. So that's DTX-3, U. S. Patent Number 4,314,081? Is that what you're referring to?

A. Right.

Q. Now, is the 08 patent also -- well, strike that.

Does the '081 patent cover atomoxetine, to your knowledge?

A. Yes.

Q. Now, what does this disclosure, what does the '081 patent say about using atomoxetine in any particular dosage form?

A. It states in a couple of different places. One -- let's say between 50 and 65 lines, it discusses, can be mixed with starch binders formulating tablets, they may be stored, it can be used in telescoping gelatin capsules, and it can be administered intramuscularly, intravenously, or subcutaneously.

Q. Do you know if this particular patent was directed toward using atomoxetine toward treatment of ADHD?
A. It was in particular as an antidepressant or psychotropic agent.
Q. Now, looking at this disclosure, is this disclosure sufficient to make it possible for a person of ordinary skill in the art to formulate atomoxetine into a suitable dosage form for parenteral administration?
A. No.
Q. What is parenteral administration?
A. That's where you inject something into the body.
Q. And why -- please explain your answer. Why is this disclosure not sufficient?
A. Well, all it describes is that you can do it. It doesn't provide any example of how to do it.
Q. Is there any information about stability?
A. No.
Q. Any information about any salt, particular salt form that you would use?
A. I don't believe so.
Q. Does it mention anything about buffers?
A. No.
Q. pH?
A. No.
Q. Antioxidants?

A. No.
Q. Preservatives?
A. No.
Q. Now, with respect to -- were there any other references that you came across that discussed using a propylamine for an injection or injectable solution?
A. Yes.
Q. And where is that information found?
A. In Exhibit 166, the '624 patent, column 9, lines 36 to 55.
Q. All right. Are you referring to Formulation 7?
A. Correct.
Q. And what is Formulation 7 directed to?
A. It's directed to an intravenous formulation.
Q. And do you know to whether or not -- is it used for treating any particular disorder?
A. I believe '624 is written for norepinephrine inhibitors or -- some -- some -- a number of these molecules can treat any kind of neurological imbalance is the term they use.
Q. Do you know if it's specifically directed to depression?
A. I -- it probably is, yes.
Q. Do you know if it's directed to ADHD?
A. No.

Q. Is it directed to ADHD, this particular patent?
A. Is it? I don't know. I don't think so.
Q. Now, in your review of Formulation 7, did you reach an opinion as to whether or not this formulation by itself would have made it possible for one of ordinary skill in the art to make an intravenous solution containing an effective amount of atomoxetine?
A. Repeat the question.
Q. Did you reach an opinion as to whether or not the disclosure in Formulation 7 was sufficient for one of ordinary skill in the art to practice the invention of the '590 patent?
A. Yes.
Q. What is that opinion?
A. It's not. It's not. Not.
Q. It is not.
A. Not.
Q. Okay. Why is that -- why is that so?
A. There's really -- there's no stability information, no salt buffers. The concentration is -- is kind of low for an IV drip. There's no antioxidants, preservatives. We don't know what the blood levels would be. We don't know what the dosage amount for ADHD would be.
Q. Now, in dealing with injectable solution, why is knowing the blood level of active ingredient important?

A. You'd have to relate the dose to the blood level, and we don't have that data.

Q. Now, given the information that you've -- given the information that's contained in the '590 patent as well as the information that you see in Formulation 7 and the '081 patent we just talked about, what other -- what, if any, experiments would one need to carry out in order to practice an invention of the '590 patent?

A. On the next slide there, it's a pathway for someone to use to develop a dosage form or dosage forms for atomoxetine.

Q. All right. Well, we're referring to slide 35.

Just like the other schematics that we looked at, is what you're illustrating here how one would go about, how one of ordinary skill would go about preparing a viable dosage form?

A. Yes.

Q. In this particular context, what do you mean by a viable dosage form?

A. We'd like to develop a system which we could administer to a patient to treat ADHD.

Q. All right. Now, let's just start with the selecting of atomoxetine -- the selection of the form of atomoxetine. And does the '590 patent provide any guidance in making that selection?

A. No.
Q. So how does one skilled in the art go about selecting an appropriate form of atomoxetine for injectable solution?
A. We went back to the literature and we tried to see what literature was present. We combined that with my experience, knowledge, and tried to develop a chart or a flow path for development.
Q. Now, would you select hydrochloride as your salt?
A. Yes.
Q. And why would you do that?
A. It's a simple salt that had been used before, and it's going to be soluble.
Q. It's fairly soluble?
A. Yes.
Q. Soluble in -- can you explain -- what do you mean by --
A. It's water-soluble, about 25 milligram per ml, so we could -- it would be -- has adequate solubility.
Q. All right. So you would choose the hydrochloride salt as your starting point.
A. Yes.
Q. Now, why does one skilled in the art -- now, you identified two types of tests, solubility and sterility. Why does one skilled in the art need to carry out the stability test?

A. To make sure that it's stable while in use.
Q. I'm sorry, I meant to go back. Let me start over again, Dr. Johnson. I apologize, because I was one slide ahead. So let's just take a look.
You would begin with the hydrochloride form of atomoxetine in this case?
A. Yes.
Q. And over there, you have three types of tests where you select your atomoxetine salt, solubility, stability, and purity.
A. Right.
Q. So if you have atomoxetine hydrochloride as your starting point, would you still need to carry out these tests?
A. Yes.
Q. Why is that?
A. You're going to test -- you're not going to -- you're going to have to get a new lot of raw material, you're going to confirm that your lot of raw material or lots of raw material are pure, you're going to confirm that the solubility is as specified in probably some literature, and you want to make sure that it's sufficiently stable.
Q. And just, can you just generally just describe how one of ordinary skill in the art would conduct these three tests?

A. In solubility, we look at solubility versus pH so we can arrive at what's the best pH. We look at it with probably some antioxidants and some buffers because we probably put it in some kind of isotonic system. We look at light stability to see whether we have to package it or put it in a -- protect it from light in some way. And we'd see how easy it's oxidized.

Q. And with respect to purity, what would you do in that?

A. It has to be pure. It has to be a hundred percent, close, or close to it.

Q. Why does it have to be so pure?

A. Because you can't administer degraded drugs.

Q. Now, with respect to the selection of the form of atomoxetine or in this case analyzing atomoxetine hydrochloride salt, in this particular case, you have it described in slide 35 as an iterative process.

A. Right.

Q. Why is that?

A. Because you're going to look at a variety of buffers, probably, and other raw materials.

Q. When you say "other raw materials," what do you mean?

A. Well, you would probably look at several buffer systems. You look at buffer capacity, we'd look at not just -- so at this point, we don't know what buffer capacity we would have to have. We don't know the amount of antioxidant

we would need. We don't know any of these things.
Q. All right. So now with respect to -- now, after you actually conduct the solubility, the pH test, the stability test, the purity test, what would be the next step?
A. We start building the preliminary formulation with all those additives together.
Q. Okay. So now with respect -- now we're at the preliminary formulation of the excipient selection step.
Now, if you notice at the box there, Dr. Johnson, you've identified four sub-boxes: IV Bolus, IV Drip, SC, and IM. Can you tell the Court exactly what they mean, what they stand for?
A. These are just different dosage forms that might be used to administer atomoxetine. If we had IV bolus, we would actually have a higher concentration in the liquid.
Q. Well, let me back up. What is an IV bolus?
A. It's where you inject the medication, IV, intravenously.
Q. Just by way of example, someone who is treating themselves with insulin, would that -- where would that fall in this --
A. That's subcutaneous -- no, put it in the muscle. IM, intramuscular.
Q. Maybe I'm getting ahead of myself. I apologize.
IV drip; what does that mean?

THE COURT: I'm still not sure what IV bolus is.

MR. PARKER: Okay.

Q. So could you go back and define for the Court, what is an IV bolus?

A. It's where you take the drug, put it in solution to be buffered, but you inject it intravenously in one dose over a short time.

Q. And can you describe, what is an IV drip?

A. That's where you drip it in slowly, typically in conjunction with another IV that's already hooked up. He'll have a bag dripping in, somebody that's already hooked up to IV, and then you'll hook up the rest of the medicament, which drips in.

Q. And you have the letters "SC" in one of the boxes. What does that stand for?

A. Subcutaneous.

Q. And what is that?

A. That's where you just put it under the -- under the tissue, but it's usually probably in the arm. Like most allergy shots are given subcutaneously. It's not into the muscle, it's in the fat layer, under the dermis.

Q. And then you have the letters "IM." What do they stand for?

A. Intramuscular. That's when you put it in the muscle.

Q. All right. Now, you chose in your slide, Dr. Johnson,

IV drip. Why did you choose that one?

A. Because that was pretty simple.

Q. And would that be the one one of ordinary skill in the art would first look to?

A. He would look at probably the dosage form he found was most -- made most sense.

Q. So when you say it would be pretty simple, are you just saying -- what do you mean by that? It makes more sense? Just, can you clarify it?

A. I had to pick one. I didn't want to go through four different ones.

Q. Okay. But in your view, this would be the one one of ordinary skill in the art would try out first?

A. Yeah, because it doesn't have any particular attributes of, it's going directly into the muscle, do I need to worry about irritation or burning? It's going to be diluted before it goes in, so it's somewhat simpler.

Q. Now, what you have done, you laid out a series of tests in terms of developing and working out your preliminary formulation and excipient selection. Could you just state for the record what those tests are? You don't have to describe them right now. Just tell us what are the names of these tests.

A. Isotonicity, stability, solubility, freeze/thaw, light, oxidation, buffer, preservative.

Q. Now, I know you've discussed some of these tests and they're probably a little bit similar, but let me just see if we can go through these relatively quickly.

What is isotonicity? Why would one of ordinary skill in the art evaluate that, and how would they go about doing it?

A. You try to combine ingredients so that it's isotonic, in other words, the same osmotic pressure as blood, so that it won't sting when you put it in or cause untoward reaction.

Q. And how would they go about assessing that?

A. You can compare the osmotic pressure. There's various devices to do that.

Q. That were available in January of 1995?

A. Yes.

Q. Now, what about stability? Just quickly, why would one skilled in the art assess that, and how would they assess it?

A. They would put it in various vials, put it in conditions of different temperature and flood it with oxygen, you flood it with light. You do different things like that to see was it susceptible to degradation.

Q. So you're looking for degradation under certain conditions.

A. Right. Right.

Q. Now, solubility, again, I know you've talked about that before. Just generally in this context, why would you look at that and how would you go about assessing it?

A. You'd reconfirm the solubility that you might have seen in a publication, make sure that it's still around 25, 27 milligrams per ml and then you'd see the effect of change in pH, and you'd also look at the stability and the changes with pH.

Q. Okay. Now, with freeze/thaw?

A. Any liquid like this that's going to be injected, you always do a freeze/thaw. In other words, you freeze it, you put it back in room temperature, make sure it comes back in solution, it doesn't develop some kind of untoward precipitate that doesn't redissolve.

Q. Light?

A. A lot of these are in vials, which are clear, so you want to make sure that you don't need a cloudy -- that you don't need to protect it from light.

Q. Now, you have oxidation.

A. Yes. It would be subject to oxidation to make sure that that medicament stays pure as -- through the course of use.

Q. Then you have buffer and preservative. Can you just quickly -- can you just generally describe why those would -- why one of ordinary skill would make those assessments

and what they would do to carry them out?

A. You always want to buffer these systems because, if anything is likely to change, you can protect that with a buffer. The other problem is, if you put too much buffer in, it might sting when you inject it or -- that's why you make an isotonic, if the buffer capacity is too high. So you always try to blend these things in a way that are easy for the patient to utilize or be utilized for a patient.

Q. Now, once one -- well, you have the arrows again with the arrows, yes and no. Are you conveying that this is an iterative process?

A. It typically would be, yes.

Q. So now once this -- well, now, let's just take a look at this for a second.

Even using atomoxetine hydrochloride, and you're doing your stability, solubility and purity tests, which are above slide 35, do you have any idea how long it would take one of ordinary skill in the art to carry out those tests?

A. From where to where? From preliminary -- probably three months plus.

Q. And now with respect to developing a preliminary formulation with all your various excipients, the selection of excipients, how long would that process take one of ordinary skill in the art as of January 11th, 1995?

A. Say about three months.

Q. So now once you've completed that aspect of the process, development process, what is the next step? What happens next?

A. We'd refine the formula so we can test it in vivo.

Q. Okay. So you refine the formulation, and you have on the slide -- can you tell us what you have underneath the --

A. We refine it so that we would have a dose or a concentration per unit ml that we would feel comfortable dosing in an animal study.

Q. Now, underneath "Refine Formulation," you have stability, sterility tests. Could you tell us why one of ordinary skill would make these assessments and how they would make those assessments?

A. It's got to be sterile, so we would subject it to some kind of sterility test. Typically, it's a prepackaged test that you can do to tell whether they're sterile.

Stability, we would do the same stability tests that we did before. We subject it to heat, light.

Q. Now, would you consider these tests in terms of putting together or preparing a preliminary formulation and excipient selection, as you've laid out these tests, would you consider that to be routine for one of ordinary skill in the art?

A. No.

Q. And why would you not consider that to be routine?

A. Because you have to -- you have to -- because you're always making a decision on whether or not these things are satisfactory. I mean, some of the steps, you're going to go, like putting the samples at station, taking them off station, do some of the physical testing is fairly routine, but sooner or later you have to make a decision, is this satisfactory, is it unsatisfactory, and it takes a fair level of skill to do that.

Q. Now, also with respect to above on slide 35 where you have those three tests, pH solubility, stability, and purity in connection with selecting the form of atomoxetine solvent, would you consider that to be routine for someone of ordinary skill as of January 11th, 1995?

A. No.

Q. And can you please explain?

A. The purity test is fairly sophisticated. You have to make sure you have a very solid analytical method. You have to have -- make sure it's a hundred percent. You probably are going to have to create some reference standards. So there's a number of aspects that are going to go into that.

Q. Okay. So once you've -- you've now refined your formulation -- and by the way, is that -- you have that also, is that indicated -- on your slide 36, are you indicating that process, the refine formulation as being an iterative process?

A. Yes.
Q. All right. Once you refine the formulation, what would one of ordinary skill in the art do next, or what would be the next step?
A. You refine the formulation, make sure it maintains its stability and sterility, and then you'd try to do an animal PK study.
Q. And what's the reason for doing an animal PK study?
A. You try and develop a relationship between the dose and the blood level and --
Q. And you have a circular arrow next to that. What is that intended to convey?
A. It possibly could be iterative.
Q. All right. Now you've gone on, you've carried out the animal PK studies, and what's next?
A. You can do a human PK study.
Q. And why would you want -- why would one of ordinary skill in the art -- well, why would those studies be carried out?
A. You don't know the dose, and we want to get a relationship between an injected dose and the blood level.
Q. Okay. Once you've conducted those PK studies, what would be next?
A. We would do a human efficacy study.
Q. And what would be the objective? What are you trying

to determine in connection with those studies?

A. Determine whether or not we can satisfy claim 1 of the patent, '590 patent.

Q. Now, you're not laying on process to prepare a dosage form that's going to be approved by the FDA for commercial marketing, are you?

A. No, but it would probably be one that we could also utilize in many of our other human PK studies, so...

Q. Now, how long would it take to carry out this aspect of the process? This is the preliminary formulation and excipient selection.

A. I think I said about three months.

Q. Okay. And how long would the animal PK studies take?

A. You could probably do those in two to three months.

Q. And the human PK studies?

A. Probably three to six months.

Q. And the human efficacy studies?

A. Probably six months.

Q. Now, with respect to the part of the process where we refine the formulation, approximately how long would that take one of ordinary skill in the art as of January 11th, 1995?

A. One to three months. If it's a liquid, we can accelerate some of the stability tests. It's not as time-consuming as with a suppository.

Q. Just back to predictability, is there any way for one of ordinary skill in the art to predict compatibility of atomoxetine hydrochloride, for example, how it would interact with any particular excipients without actually conducting a test to see what it would do?

A. After the first three months there in that top -- once you get a -- once you know what the solubility, pH solubility in water is and the stability along with that various pHs, you can probably make a fair guess as to some of the ingredients you're going to use in the preliminary formulation excipient section, but then you have to do that and confirm what your prediction might be. So you really have to carry that work out.

Q. But would you be able to predict the compatibility of the preservative with the active ingredient without actually conducting the test?

A. No, we carry it out. But at that point, you probably predict what pH you want to work with.

Q. And again, with respect to the PK studies, human PK studies and human efficacy studies, is there any way to predict the outcome of these studies without actually conducting them?

A. No.

Q. Do you know if there's any way to predict what amount of atomoxetine hydrochloride in an injectable solution would

be effective to treat ADHD without conducting any of these tests?

A. No.

Q. Now, Dr. Johnson, on slide 35, as you are describing other forms of injectable solutions, you mentioned IV bolus, subcutaneous, and intramuscular.

Now, with respect to the quantity of experimentation and the predictability in working with these types of dosage -- let me back up.

With respect to quantity of experimentation and the unpredictability that you pointed out as it concerns developing the IV drip, would that amount of experimentation and that level of unpredictability, would that be the same, or less, or more for the IV bolus?

A. It would probably be more for the IV bolus and the other two systems because in those systems we're going to have more concentrated drug, we're going to worry more about irritation, and we'll be concerned, like an IV bolus, how fast can we actually inject the material. So I'd certainly want to do an animal study on those systems.

Q. Now, what about subcutaneous; would it be the same, more, or less?

A. We'd want to inject it subcutaneous and then evaluate the site. We'd biopsy it and look for any problem.

Q. Let me back up. So the amount of -- with respect to

quantity of experimentation and the level of unpredictability that you described with the IV drip, would that be more, the same, or less in connection with developing a subcutaneous formulation?

A. It would be less.

Q. Less.

And what about intramuscular; would it be more, the same, less?

A. It would be similar to subcutaneous.

Q. Now, you said it would be less. How much less would it be relative to the IV drip?

A. It would be more. These would be -- these three others would be somewhat more than IV drip, and it would be, let's say -- the animal studies can be more extensive.

Q. More what?

A. Extensive. It would probably take another month or so.

Q. Now, just, in your experience, when developing an injectable solution, what are some of the challenges that one would encounter or could encounter?

A. Oxidation is often a problem. Once -- and stability is often a problem, because once you're in a liquid, it's much more difficult than a powder that's -- where there's no moisture. So stability is often one of your biggest problems.

Q. Is compatibility a potential problem?
A. It can be. That's why we'll study it. But we mostly will pick things we don't think it will be incompatible with.
Q. Now, Dr. Johnson, again, based on your consideration of the Wands factors, your review of the '590 patent, your review of the '081 patent, and also your review of the '624 patent, have you come to an opinion one way or the other as to whether or not undue experimentation would be required to practice the invention using injectable solution?
A. Yes.
Q. And what would your opinion be? What is your opinion?
A. That would require undue experimentation.
Q. Now, with respect to the slide dealing with injectable solutions, was that slide prepared under your supervision and direction?
A. Yes.
Q. As well as, it was prepared for your testimony today, you had it prepared for your testimony today; right?
A. Correct.
Q. Dr. Johnson, let's move on, and we're getting through this, so this is very good.
Let's talk a little bit about sustained release formulations.
Now, what is a sustained release solid dosage

form?
A. It's a dosage form where the drug is typically embedded in some matrix which slows the release down.
Q. Now, does the prior art describe a sustained release dosage form comprising atomoxetine?
A. Yes.
Q. Have you evaluated that --
A. Yes.
Q. -- that piece of prior art?
A. Yes.
Q. And can you identify for the record what that piece of prior art is?
A. It's Exhibit 165, so --
Q. That's U. S. Patent 4,847,092?
A. Correct.
Q. Now, you mentioned that it discloses a sustained release formulation. Is that a capsule formulation --
A. Yes.
Q. -- do you know?
A. Yes.
Q. Where in the patent is that found?
A. It's -- Example 4 and 5 give examples of where he heated up this waxy material and embedded the drug.
Q. So this is Example 4 and 5 in the -- what we're referring to as the '092 patent?

A. Right, and it's column 4, lines 30 to 47, and then the Table II is in column 6, lines 3 to 18.

Q. Now, in your evaluation of this formulation, did you reach any conclusions as to whether or not this disclosure was sufficient to allow one of ordinary skill in the art to prepare a sustained release formulation comprising a sufficient amount of atomoxetine to treat ADHD?

A. No.

Q. And why is that?

A. It doesn't -- it uses three dogs. There's no statistical evaluation. There's no stability data. It's really a sample they prepared of a few capsules, it appears, and gave these to some dogs, and we would expect if you embed the drug in wax, it will retard the release. The problem is, we don't know, we have no idea how this is going to relate to human dose or human response. A dog isn't particularly a good model for sustained release.

Q. Do you know, is there an animal model for ADHD?

A. Not that I'm aware of.

Q. Now, you said that there was -- you mentioned something about this statistical analysis. Can you just explain what you meant by that? In other words, you were saying -- it wasn't sufficient statistical analysis?

A. I don't believe there's any. I think there's an average.

Q. There was an average. So what is your -- do you take -- what is your issue with that with respect to having -- concluding that one of ordinary skill in the art would not be able to make a sustained release formulation based upon this disclosure?

A. We don't know what the variability is, and if the variability is high, it's probably not going to be appropriate.

Q. When you say you don't know what the variability is, can you just be a little bit more specific? What do you mean?

A. Well, if the dosage forms are all the same, if it releases and it's absorbed, and nearly, you know, plus or minus five percent in most of these -- these data points, that's pretty good; but with only three dogs, that's really not enough.

Q. Now, can you refer your answer -- I mean, can you -- with respect to the answer you just gave, can you correlate that to Table II up on your slide 37?

A. Yes, in Table II, what they have are the blood levels after these times, which appears to be an average microgram per ml of the drug. But there's -- but there's no standard deviation, so we don't know if it's .05 plus or minus 10, or we don't know any of these numbers, .8 plus or minus 10, or 20. We have no idea. So we don't know what the variation

is.

Q. So is this just simply, is it a formulation where they just included I believe atomoxetine in a wax and they add anything else to the formulation, do you know?

A. They I think added -- they added a cellulose to one of these.

Q. Do you know what the purpose of adding cellulose was?

A. It probably would create some porosity in the matrix.

Q. Some what?

A. Porosity, when -- and -- because 591 is what they used. That's somewhat hydrophilic, so it would probably create porosity so water can get in this wax and the drug can diffuse out.

Q. What is the name of the wax? What is the name that they use?

A. Gelucire, and the grade is 46/7.

Q. Now, Dr. Johnson, given the information that's contained in the '590 patent taken together with the information that was found in the '092 patent, which is DTX-165, and I'm referring to Examples 4 and 5, given that example in hand, what experiments, if any, would one of skill in the art need to conduct in order to prepare a viable sustained release atomoxetine formulation?

A. If you look at the next slide --

Q. Okay. Could you just -- is this a slide that was

prepared under your supervision and direction?
A. Yes.
Q. Now, let's just start with the selection of atomoxetine form.
Does the '590 patent provide any guidance in making that selection?
A. No.
Q. Now, with respect to the '092 patent, I believe, what form of atomoxetine did they use?
A. They used the hydrochloride.
Q. And that was used in dogs.
A. Correct.
Q. Now, so you have there as your first step selecting a form of atomoxetine salt.
So with that, where would one of ordinary skill in the art, where would they begin?
A. I think you'd probably start with the hydrochloride.
Q. Why is that?
A. Well, you typically can sustain the release of a salt that soluble for at least 12 hours.
Q. And so if you start with a hydrochloride salt, and below this, you have a series of tests, and I think we've seen these before, crystal purity, solubility, stability, dissolution, and you also have particle shape and size -- did I read that correctly?

A. Yes.

Q. Again, would developing a sustained release solid dose form, could you just explain -- let's just go through them quickly each one.

Crystal purity: Why is that an assessment that needs to be made with this particular dosage form, and how would one with ordinary skill go about doing it?

A. You have to administer a pure drug. The word the FDA uses is "unadulterated."

Q. Now, what about solubility; what do you have to assess there?

A. It has to be -- you have to have an idea of the solubility of the drug, and that helps guide you whether you're going to -- if it's more soluble, you are more likely to put insoluble ingredients in your dosage form.

Q. And stability; what's going on there? Why do you have to look at stability?

A. We like to -- we want to know the solubility as a function of pH, and we want to know the stability as a function of pH, and we want to know the stability with our excipients and as a raw material.

Q. Dissolution; why do you have to assess dissolution?

A. We want to look if it has any unique or particularly unusual properties, like some of these -- some of these compounds will, even if they're fairly soluble, will

aggregate, and they won't dissolve quite as you think they might.

Q. And in particle size and shape?

A. That will affect the dissolution rate.

Q. That will affect the what?

A. The dissolution rate.

Q. Is that an important factor?

A. Yes.

Q. Now, does the '092 tell you anything about particle size and shape?

A. No.

Q. Is that something that one of ordinary skill in the art would need to know in developing a sustained release soluble dosage form?

A. Yes.

Q. Now, as with your other schematics, in selecting the form of atomoxetine salt or at least assessing it for purposes of using it for a solid -- for a sustained release solid dosage form, on slide 38, again, you have arrows, and you have yes and noes going in various directions. Just what do you intend to convey there?

A. If we find any untoward events, we would then probably have to go back and do something. In other words, if the crystal wasn't pure, we'd have to purify it before we did the rest of the work.

Q. And are there other things that could go in a certain direction that would require repeating certain tests?

A. Yes, if it's a relatively unstable compound, as you go to solutions or liquids, we'd have to judge whether or not we would have to -- what other ingredients we might mix with.

Q. And just by way of example, particle size and shape, how would that affect it?

A. Well, they affect flow, so if it's in a powder that is a very big particle and we put it in with our other powders, it will probably segregate or separate and we won't be able to use it properly. So it has to be small enough so we can mix it and big enough so it will flow.

Q. And none of that information is found in the prior art; right?

A. No.

Q. Now, so, then, dealing with the portion of your slide, the process, that would be an iterative process?

A. Yes.

Q. All right. So now that you've conducted all those tests and you've gone through and made your -- you're ready to go to the next step, and what would that be? Once you've carried out this crystal purity, going through the particle size and shape on slide 38, what would be the next step?

A. We'd want to make out some preliminary formulations

and look at, characterize their dissolution. So we'd try to pick, select a dosage form system which we're familiar with and run through. Just -- you wouldn't do five different types. You may do one or two.

Q. Now, below that preliminary formulation and excipient selection stage, you have five boxes underneath that. You have coating, beads, hydrogel, osmotic, and ion exchange. Could you briefly just describe to the Court what types of systems are these? So starting with coating, what is that?

A. That's where you use a coating to really control the release. You control the release from a bead or you can control the release from a tablet, but you primarily do it through the composition of the coating. In other words, your core would be pretty soluble, but you control the rate of release with the coating.

Q. Now, you mentioned beads, but you also have beads up there on the slide so --

A. Right. That's where -- you can do it two ways. You can coat, make a bead that's very soluble, and then you can coat the bead and have the drug release modified by the way you control the -- coat the bead. You can also make beads that the cells are formulated so they dissolve rather slow.

Q. Now, hydrogel; what is that?

A. It's usually like a cellulose or methylcellulose or something related which when it hits the water it forms a

gel, and then this gel mass is hydrated and the drug will slowly diffuse out of this gel.

Q. Now, the system you saw in the '092 patent; is that a hydrogel system?

A. No, that's -- I guess we don't have that up there. That's a wax matrix system. That's really a wax, and then you modify the wax porosity with different materials, either hydrophilic or phobic, depending on your drug, and you control the release that way.

Q. Now, you have osmotic systems. Just describe that.

A. Those are systems where -- they can be -- you can have an osmotic coating or like the Alza system where they have a matrix which is coated and then they put a hole in, and the osmotic pressure forces the drug up.

Q. And ion exchange?

A. That's like one of these resins where you usually absorb the drug onto this resin, and you can control the release off the resin, or you can coat the resin and control the release that way.

Q. All right. Now, you're going in the direction of a hydrogel. Why did you select hydrogel?

A. It's a -- I thought it was one of the more simple ones. It's commonly used.

Q. Now, okay, so we're going with the hydro developing hydrogel. Now, what would be the next step that you have

laid out in slide 39?
A. We have like a basic formulation and then we'd vary it with different parameters, concentrations of drug, concentrations of other excipients. We'd make it more hydrophilic, more hydrophobic, and then do dissolution studies on this group of formulations to see where we were.
Q. And you have two tests underneath the "Multiple Formulation With Different Release Rates" step.
A. Yes. While we were evaluating our dissolution rate on these different systems, we'd also study the stability to see how it changed.
Q. Okay. To see how what changed?
A. How these dosage forms might change. Their release might change on day one, or if we put it at 40 degrees for a month or two months, how it would change, because those forms have to be stable throughout these periods, at even elevated temperatures, to be one that we would want to use.

So in this case, we're concerned about stability of the drug as well as stability of the release rate.
Q. Okay. Now, just walk us -- let's go, continue going through the process.

You have -- well, I take it, then, the multiple formulations with different release rates, you have the stability and dissolution rates. Is that an iterative process, too?

A. Yes, that's a cycle you most likely would go through several times.

Q. Now, the next step you have down is "Human Pilot Studies." You have "2 Dose vs. IR." Can you explain what you mean by that?

A. You would probably want to try at least -- at this point, we would use in vitro dissolution testing to try to predict rates which we felt were suitable. So we pick one that's slower and one that's faster, and we do a pilot study to see approximately where we are as related to amount of drug released, as amount of drug absorbed, and try to get an idea, is this near the model or the line where we want it to be released. Is it releasing the way we need to have it released.

Q. Now, you have this "2 Dose vs. IR." What does IR stand for?

A. Immediate release.

Q. And why are you making that comparison?

A. That's typically what you do as you -- you'll run a study versus immediate release and look at that absorption. We probably do it with multiple release of two dosage forms, probably at zero and four, zero and six hours, and then we'd run our sustained release, see do we get the same blood levels. We're trying to -- what we're trying to do with the sustained release is reproduce the current dose.

Q. And then when you refer to sustained release, just generally, what does that mean, sustained release?
A. It's where you're taking the drug and it's not immediately releasing, you're changing the rate that it's released.
Q. Now, you have that also down as iterative process, the human pilot studies. Why is that?
A. Because at that point, you're really not sure how you want to release, but from that, you should be able to judge how to make it the next time so that it would be released properly.
Q. Now, --
A. We usually bracket the release rates you want, and you do multiple studies and you pick the one nearest the level you want.
Q. Now, going down to the next step, can you just describe what that entails?
A. We would do a PK study and look at extent of absorption, rate of release of the dosage form, and determine whether or not we thought it was delivering the drug as we purport it to be.
Q. Now, to make all these assessments, at least with respect to PK or human pilot studies, you need analytical assays; correct?
A. Right.

Q. What type of assays would you need or what types of assays would need to be available to one of ordinary skill in the art to carry out these types of tests?

A. We'd need to be able to analyze the drug in the blood.

Q. Now, with respect to the human PK comparative studies, you also have that circular arrow there. What is that intended to convey?

A. Once we do that, we may have to go back and modify the amount of drug and size of the dosage form and the release rate.

Q. So it's an iterative process there as well?

A. It can be an iterative process. If we could replicate the release of the drug and the blood levels from the oral versus the multidose, then we have a good chance to get this approved on bioavailability studies. If we don't, we're going to have to do efficacy studies.

Q. Now -- well, then you have down there, you have efficacy studies. Just explain what the objective is there for those tests.

A. For example, if our dose -- let's say a release from the drug or the area under the curve was maybe 20 percent or -- let's say 20 percent less than if they did multiple doses. I think you'd probably have to do a human efficacy test.

Q. But what is the ultimate goal of carrying out these

efficacy tests, and what are you trying to determine?

A. To evaluate the drug release.

Q. For purposes of what?

A. We have to evaluate whether or not this drug can treat ADHD.

Q. And determine whether or not you actually have an effective amount for the dose?

A. Correct. Correct.

Q. Just to go back.

Okay. So just, how long would this -- for one of ordinary skill in the art, how long would this process take? I'm trying to point to it here, where it says "Selecting Form of Atomoxetine Salt," this particular aspect of the process, how long would that take?

A. Probably about three months.

Q. And now when you're developing and dealing -- well, focusing on your multiple formulations with different release rates, that test, how long would that take for one of ordinary skill in the art?

A. Three to six months. We want to get a pretty good idea of the drug release from their dose if it wasn't changing over time, so you're going to have to do your stability studies for several months.

Q. And just a sense of how long it would take to carry out the human pilot studies.

A. Well, the pilot study, maybe three months.
Q. The human PK comparative studies?
A. Probably three to six months.
Q. And the human efficacy studies?
A. Six months more.
Q. Okay. Now, when we talk about coating, you have other different systems for sustained release forms. You have coating, beads, osmotic, and ion exchange. We didn't talk about them in great detail, but we'd probably be here forever if we did.

Would the quantity of experimentation and the level of unpredictability -- well, let me back up. I didn't talk about that. Then let's just focus on unpredictability.

You described a fair amount of testing that would be involved in preparing sustained release dosage forms; correct?
A. Yes.
Q. Now, given the prior art that you evaluated, okay, could anyone -- could one of ordinary skill in the art be able to come up with a sustained release dosage formulation without conducting any of the tests that you've just described?
A. No.
Q. Is there any way to predict what atomoxetine hydrochloride would do in a particular dosage form if it's

injected into a patient -- I'm sorry, if it's administered to a patient?

A. Say that again.

Q. Would one of ordinary skill in the art be able to predict how a sustained release dosage form would behave once it's administered inside the patient?

A. Well, your prediction is going to be that it will meet that need, but it's not likely that you're going to make it the first time.

Q. And as far as selecting excipients and as far as looking at stability, I mean, these tests would have to be carried out; you can't predict those, I mean, you can't predict the outcome of those tests.

A. You keep doing these studies because you're always changing things, and it's typically not predictive.

Q. Now, so now going to these other systems, the coatings, the beads, the osmotic, and the ion exchange, then, with respect to the quantity of experimentation and the unpredictability you described for the hydrogel, okay, is that more or less the same for the coating?

A. They're comparable. I don't like to -- I don't know that I can say that they're -- in this case, a lot of them I can tell pretty much their -- it depends on what the skill of the formulator is: Has he made these a lot of times or not. In other words, we can probably do beads, coated beads

as fast as we could do hydrogels, but that's probably not the case for most people.

Q. What about an osmotic system or an ion exchange system?

A. There are a lot of patents in those areas, so they're generally reported.

Q. Okay, but assuming there were no patents in the area and you were free to go ahead and do it, in terms of the amount of experimentation and unpredictability, would it be about the same as the hydrogel, or less?

A. The coated tablets where you have an osmotic tablet wouldn't be as -- too difficult. The problem there is actually making them with the right kind of hole in them consistently and have the coating being -- integrity of the coating sufficient so that it doesn't crack, break, or allow unwanted moisture into the system.

Q. Now, early on, from a formulating standpoint, earlier, you testified that there were two populations of individuals in terms of how they metabolize atomoxetine. Do you remember that testimony?

A. Correct.

Q. Does that fact have any -- what effect, if any, would that have on one of ordinary skill in the art who's trying to develop a sustained release solid dose form?

A. I think you'd have to design a sustained-release

system probably based on one of the groups.

Q. So one sustained release dosage form in your view for an extensive metabolizer would be suitable for a poor metabolizer?

A. No.

Q. Are you aware of any other challenges that one of ordinary skill would encounter in formulating a sustained solid dose form?

A. I think that the difficulty is going to get similar absorption from the sustained release system that you get from the multidose tablets, fast release.

Q. Now, -- well, you mentioned dissolution. I just want to make sure we covered it.

Okay. You mentioned dissolution in both the selecting the form of atomoxetine salt level or the step in slide 38, and also, you mentioned dissolution rates in connection with multiple formulations with different release rates. I'm not sure if I covered it, but I just wanted to ask you, Dr. Johnson, why would someone of ordinary skill in the art carry out those tests?

A. The first is on the raw material and the second is on the dosage form, and the dosage form, we measure that so we can assess the performance of the dosage form.

Q. Now, Dr. Johnson, based on your consideration of the Wands factors and also your evaluation of the state of the

prior art, which included the '590 patent, I believe the '624, and there may have been other patents, but based on your evaluation of the state of the prior art, did you reach an opinion as to whether as of January 11th, 1995, undue experimentation would have been required by a person of ordinary skill in the art --

A. Yes.

Q. -- to prepare a sustained release solid dosage form having sufficient atomoxetine to treat ADHD?

A. Yes.

Q. And what is that opinion?

A. It would take undue experimentation.

MR. PARKER: Slide 21, please.

Q. Now, Dr. Johnson, earlier, you testified, it may have been Wednesday, that in your view, based on your review of the prior art and your reading of the '590 patent that you concluded that immediate release capsules and tablets containing atomoxetine hydrochloride would not require undue experimentation. Do you recall that?

A. Yes.

Q. And can you explain to us how you come to that conclusion?

Why don't we start off with, was there information in the prior art that led you to that conclusion?

A. There was information in the prior art and my own

experience that allowed me to come to that conclusion.
Q. Okay. Now, with respect to the prior art, do you have in front of you DTX-86, which is a Canadian patent?
A. Yes.
Q. Now, does the Canadian patent disclose any formulations containing atomoxetine hydrochloride?
A. Yes.
Q. What formulations does it disclose?
A. It has capsules, tablets, --
Q. All right. Well, let's just focus on capsules and tablets.

Now, you evaluated these formulations; right? Can you find them?
A. They're on page -- 1,181,430, page 22 of the patent.
Q. Page 22 of DTX-86, page 22?
A. Correct.
Q. And you evaluated these formulations?
A. Yes.
Q. And what is it about these formulations, among other information that you had, including your experience, that led you to conclude that one of ordinary skill in the art would have been able to develop these dosage forms without undue experimentation?
A. These are very simple systems, they're dry systems, and it's unlikely to be unstable in this kind of a system.

Q. And why is that?
A. Because they're dry. There's not enough moisture present for anything to react -- for something to react, you typically have to have mobility. So you have mobility which can dissolve the drug so it can react and degrade. But if you have no water that's really free, it's unlikely to have degradation.
Q. Now, with respect to the effective amount, the appropriate dose for the tablet, now, the patent provides dose information, does it not, the '590 patent?
A. The '590 patent provides dosing information but it doesn't specifically say whether that dosing information is -- what it's related to. But we're assuming that where they got their dosing information was from the work probably done earlier for depression because they're using the same dosage range, and some of these other publications also use that dosing range, so I'm making that leap of faith.
Q. Well, let me put it this way. So based on your review of the prior art and your review of the '590, is it your view that the dose range described in that patent is directed to capsules and tablets?
A. Yes. Yes, because the capsules in these publications -- the dose forms in those cases were capsules, and in one case, I know it was a hydrochloride salt.
Q. And did you assume for purposes of your analysis, did

you make any assumptions as to whether or not those dose amounts in the patent were directed to effective amounts for a tablet?

A. I don't know. They were just the same dose, because one was for depression, and the patent's for atomoxetine. So I'm making that leap of faith that that's comparable.

Q. All right, but is there anything else in the patent that correlates these dose amounts to any particular dosage form?

A. Well, they don't really -- in this patent, they don't specifically talk about what amount they're dosing, and they don't relate it to a dosage form, whether it's capsules or other dosage forms.

Q. But based on your assessment of the prior art, you came to a conclusion that it was directed to capsules and tablets? Is that fair?

A. I'm making that assumption, yes.

MR. PARKER: Slide 47.

Q. Now, as part of your analysis, did you assess whether or not there was any information relating to whether or not atomoxetine presented any special problems in formulating dosage forms comprising atomoxetine hydrochloride?

A. Yes. The Exhibit 162 has a number of pages which identify various problems or potential problems that you might have in formulation of atomoxetine hydrochloride.

Q. And you're referring to DTX-162?
A. Right.
Q. Do you have an understanding as to where the document came from? Was it produced in litigation?
A. Pardon me?
Q. Do you have an understanding as to where Defendants got a copy of this document?
A. I assume it was produced for litigation.
Q. Do you know who it was produced by?
A. I'm not sure.
Q. What is the title of the document?
A. "Atomoxetine Drug Delivery Line Extension Opportunities."
Q. Is it your understanding that this is a document that came from Lilly's files?
A. That's my understanding.
Q. Now, you have there --
A. I'm assuming it's Allen. His name is on the document.
Q. Are you talking about Albert Allen?
A. I don't have a first name.
Q. Now, you have there on your list, you have high solubility, and you have suspension.
A. Right.
Q. Could you tell us -- well, where is that found in DTX-162? I'm referring to slide 47.

A. We found most of these in -- there's four or five pages of items which --

Q. Wherever it is, just identify in the corner that you see a confidential ST patent number, could you identify what you're looking at?

A. What pages there are?

Q. Yes.

A. I'm looking at 00769571.

Q. 769571 from DTX-162.

A. Yes.

Q. Okay. Where does it talk about high solubility as a potential problem? Can you explain -- you have on the slide "High Solubility-Suspension." Can you explain what you mean by that?

A. The high solubility is a problem because you can't make a suspension. The drug will be in solution.

Q. So your review of this document, it was identified that that was a potential problem for atomoxetine hydrochloride?

A. Correct.

Q. Now, you also have listed "Requires High Dose." Where was that found in DTX-162?

A. 571.

Q. Okay. And can you show us -- can you kind of give us a sense of where in the document? You're reading it as a

chart.

A. There's a chart under "Comments." They have a number of comments where they address issues like high dose, bitter taste.

Q. Well, with respect to "Requires High Dose," how would that have an effect, if any, on developing a transdermal system?

A. It would increase the difficulty of preparing or developing systems of transdermal delivery, thin film, pulmonary, buccal, or sub-lingual sprays.

Q. And why would that pose a problem -- well, why would that be considered a special problem, if at all, in dealing with or developing a pulmonary type system?

A. Difficulty can arise if you find or actually have one of those doses containing sufficient atomoxetine to treat. In other words, you can't, you know, if you -- if the dosage form's got to weigh a gram, you can't put a pound of powder in it. So in this case, our dosage -- for some of these, we don't have any idea what the dosage is, but I'm assuming they thought it was high.

Q. And the same, is that true for the buccal, sublingual spray?

A. Yes.

Q. Now, you have listed bitter taste. Where is that found in the document, DTX-162?

A. That's also under the "Technical Challenge" column under "Comments" on 571.
Q. Okay. This is where it says "Technical Challenges"?
A. Correct.
Q. Okay. Well, the word bitter is not there. So -- it says "taste." How did you come to the conclusion that it was bitter taste that was being referred to in this document?
A. I believe I've seen that written different places, and I know it would be bitter.
Q. Now, how is it that a bitter taste can be a problem at all in developing any of the dosage forms you'd have on slide 41, which is effervescent tablet, or disintegrating tablet, chewable and chew, a buccal or sublingual spray and nasal? How would that be?
A. They'd have to be palatable.
Q. And in your experience, if they're not palatable, is that a viable dosage form in your view?
A. Usually not.
Q. And why is that?
A. People won't take it.
Q. And is that an important consideration when treating ADHD?
A. Especially ADHD, because you have to take it for four to six weeks to see effect, you've got to take it for years,

and if it's not palatable, people just won't keep taking it.
Q. All right. Now, you've also listed metabolism of atomoxetine varies among population, and you have extensive metabolizers, EM, and poor metabolizers. Where is that identified or presented as a potential problem or a possible problem with forming a dosage form of atomoxetine? Where is this on DTX-162?
A. I think on page 574, they talk about poor metabolizer, atomoxetine, and number one, and extensive metabolizers.
Q. Okay. Let me back up. You're referring to STPAT 769574 --
A. Correct.
Q. -- point six?
A. Correct. And also document number six: "If formulation and dose regimens are to be modified, then genotypic differences will likely need to be considered - for example, delay in Tmax to improve daily coverage, will likely create very different looking profiles in EMs versus PMs. Will need to consider what impact, if any, that could have clinically."
Q. Now, Dr. Johnson, in your experience, if you have a population -- by the way, can you just tell us again, there was a difference in the level of metabolism. How different was it between EMs and PMs, based upon your reading?
A. It was substantially different. Half-life of the fast

metabolizers may be four to five hours, and the other, slow metabolizers was 17 to 20 hours.

Q. So when you're developing a modified release -- and by the way, when I say modified release form, what does that mean to you?

THE COURT: When you say it, what does it mean?

MR. PARKER: I'm sorry. What I say doesn't make a difference.

Q. Modified release; does that have a meaning in your field?

A. It means you've changed the rate that it's released from let's say -- it's been modified in some way. It could be slower, it could be faster, it could be different.

Q. So if you're developing let's say for example sustained release, and you know you have this population of different metabolizers, does that present a challenge when you're trying to develop that type of formulation?

A. Yes.

Q. And can you explain what that challenge would be?

A. I think -- if you just give one dosage form for slow and fast metabolizers, you're going to have such variability in your blood levels that you won't be able to make a prediction as to whether this is an appropriate sustained release system. I think you'd have to choose a fast metabolizer group or a slow metabolizer group and design a

dosage form for one of those groups.

Q. All right. Now, let's just go on to slide 42.

You have down pH solubility, and --

THE COURT: Is this slide 48?

MR. PARKER: I'm sorry. Slide 48. Thank you, Your Honor.

THE COURT: How much longer are you going to be with the witness?

MR. PARKER: Probably 10, 15 minutes. Just about done. Getting close.

THE COURT: Go ahead.

MR. PARKER: Do you want to break now?

THE COURT: No, you go ahead.

MR. PARKER: Thank you, Your Honor.

BY MR. PARKER:

Q. All right. So, Dr. Johnson, you have on your slide 48 "pH Solubility." Can you show us where it is in DTX-162 where that is found?

A. Page 572 in the same document: "PH solubility can complicate delayed-release formulation; not so for sustained release matrix formulations that are polymer-driven - evaluate impact of pH solubility and delivery technology select ed."

Q. Now, you have response time, four- to six-week evaluation period to determine the patient response to

atomoxetine. Where is that on DTX-162?
A. On page 570, about the middle of the column, the biggest -- the biggest paragraph, where it starts, "Prescription level data for adult patients show that 40 percent of patients discontinued Strattera within the first 30 days of the treatment."
Then down to the right side of the third line: "A four to six week evaluation period is required to determine if a patient is a Strattera responder. During the treatment initiation phase, tolerability issues predominate and can be exacerbated with a rapid dose escalation."
Q. So if it takes -- four to six weeks are required to evaluate whether a person is responding to tomoxetine, how does that from a formulating standpoint pose any challenges?
A. Well, it takes a long time to get feedback on whether your dosage form is delivering the right amount of drug in the appropriate period of time.
Q. So it would affect the length of time it would take?
A. Well, they're -- usually if you can do just a bioavailability study, you can get your data back relatively quick. If you've got to wait four to six weeks for each patient, and it takes them three to six months to enroll all the patients, it takes a long time to get your feedback back to know whether or not the dosage form you developed is going to be suitable.

Q. Is it fair to say tomoxetine is not a fast-acting drug?
A. Apparently.
Q. So does that also now have an impact on the stability of your formulation?
A. No.
Q. Well, as far as treatment goes, it's a long treatment period, and storage is important --
A. Right. Right. Storage will always be important.
Q. And why is that important?
A. Because you have to deliver an effective amount of the drugs, and it can't be degraded.
Q. And so does that have impact -- so that would fall under the category of stability?
A. Correct. You would do that.
Q. Now, you've also listed Cmax, "Small change in drug release can affect Cmax." Where is that found in DTX-162?
A. On page 570, the second paragraph, the last 10 words: "Small changes in drug release can affect Cmax and Tmax."
Q. Do you have an understanding of what that was referring to based on your understanding of this document?
A. Well, if you're trying, especially if you're trying to make a sustained release system, very small changes in the way you've released the drug can affect the maximum concentration that you have and the time you reach maximum

concentration of drug. So it affects your evaluation of sustained release, and I would think it makes it more difficult.

Q. Now, you also have listed -- you also have on your list "dosing children, challenging capsule size." And just tell us where is that on DTX 162.

A. It's the fifth -- fifth paragraph down on page 570: "Challenging capsule size; better effect in adolescents rather than in six to 12 year age group patients," which means to me the kids are having trouble swallowing the capsules.

Q. So children, at what point, at what age group do the children have to swallow capsules?

A. Their brackets were six to 12 having an issue.

Q. Now, Dr. Johnson, Plaintiff Lilly in this case has taken the position that there are no special problems, you have not identified any special problems in formulating dosage forms comprising atomoxetine or atomoxetine hydrochloride. Do you consider that to be a true statement?

A. No.

Q. Is that based upon, among other things, your evaluation of DTX-162?

A. In addition to 162.

Q. Now, I don't recall if I asked you, but I have to go back. With respect to the sustained release --

MR. PARKER: Your Honor, I'm just about done. I just want to confer. One second.

(Off the record discussion)

MR. PARKER: 541.

Q. All right. With respect to some of the prior art, additional prior art that you evaluated, Dr. Johnson, I believe you also reviewed a reference that we referred to as Chouinard.

A. Yes.

Q. And that is in your book as DTX-55.

Can you just -- did that have any -- did you consider that in your analysis --

A. Yes.

Q. -- on new experimentation?

A. Yes.

Q. What information did that reference provide, if anything?

A. It was one of those that provided information relative to treating depression in this dosage range that we've viewed before --

Q. Okay.

A. -- with the caps.

Q. Now, with respect to -- did you also consider DTX-95, which is the Farid article?

A. Yes.

Q. Now, what information did this reference have in the prior art and how -- did it have any impact -- did it have an impact at all on your analysis?

A. Yes. They used the tomoxetine hydrochloride, in one section they discuss it, and in another section they say it was a capsule. So I'm assuming that this capsule was -- was atomoxetine hydrochloride that they dosed these people.

Q. What was it that Farid showed in that paper?

A. Mainly that there are two populations of metabolizers. I believe they provided some limited pharmacokinetic parameters, but they really didn't do a lot of people. They only did -- they did multiple dose in 20-milligram and they did multiple dose 40-milligram. So you get an impression of dose, two doses in a day as well as some --

Q. Now, did it show any correlation between plasma blood levels and the amount of atomoxetine hydrochloride given to a particular patient?

A. It showed different levels because in the extensive metabolizers, the blood level is quite a bit lower.

Q. Now, on DTX-34, you recall reviewing an article authored by a gentleman named Zerbe?

A. Correct. This is actually -- I'm pretty sure this is the same population, same group of people. The difference was, this reported on pharmacodynamic parameters for blood pressure, they talked about decreased appetite, some of the

--a number of adverse experiences.
Q. So that was something you considered in your evaluation of undue experimentation?
A. Yes.
Q. Now, just see if we can -- there are other formulations, dosage formulations that you believe were also covered by the claim, the claim of the '590 patent; correct?
A. Correct.
Q. And what are those other dosage forms?
A. We could -- we could have considered fine granules, oral disintegrating tablets, chewable -- chewable tablets or a chewable mass that children could take, delayed release tablets or caplets, or entero coated matrix tablets, thin films, sub-lingual tablets, lozenges, ointments, creams, elixirs, emulsions, gels.
Q. And we did not choose -- well, why did you not choose to go through all those different formulations?
A. Well, I thought the six or eight we did was tough enough.
Q. Okay. Well --
A. But these in many senses are related in degree of difficulty. For example, a delayed release tablet/capsule or entero coated is going to be comparable to the sustained release oral dose. A chewable/chew or orally disintegrating tablet, sub-lingual tablets or fine granules are going to be

comparable to suspensions, dosage forms like that. You're going to probably have to have a insoluble salt or you're going to have to have something different. And other topical systems would be relatively similar to transdermal patches.

Q. So when you say comparable, are you saying comparable in the --

A. Degree of difficulty.

Q. And also in unpredictability?

A. In what?

Q. In unpredictability?

A. Yes.

Q. All right. Dr. Johnson, we're just about finished. Let me just wrap this up really quickly.

Now, you've showed a fair amount of schematics over the past, Wednesday and throughout the day today, and there's a lot of information, a lot of experiments carried out and a lot of data being generated, but I just want to make clear: Are you suggesting that the '590 patent contained all that information in the specification?

A. No.

Q. But what is it about the patent in your view that would require those experiments be carried out and develop those dosage forms?

A. It just doesn't contain the information necessary to

carry out the necessary work to develop these systems for treating ADHD in the practice that was claimed.

Q. And is that also because there's no working examples in the '590 patent?

A. There's no working examples. There's just a paucity of information.

Q. So in everything that you would need to carry out -- well, let me back up. So everything one skilled in the art would need to develop a dosage form of any kind, you'd have to go to -- you would have to resort to the prior art; is that --

A. Correct.

Q. Now, just the last two questions now. You recall the factor, the Wands factor dealing with breadth of the claims?

A. Yes.

Q. Now, with respect to the dosage form, did that impact your analysis in connection with undue experimentation?

A. Yes.

Q. How did it?

A. You really have these two groups of things. You've got oral products, which -- fast-dissolving products which are much more simple, and we're making a leap of faith to actually guess what the dosage would be for them. However, for the other dosage forms, we have no idea what the dose is going to be because we don't know from the transdermal

system if it's going to by 20 percent, 10 percent, 80 percent. The same with -- and sustained release is going to be also a problem. But we basically don't know any of these other doses from what the dose would be.

Q. So that factor would favor undue experimentation as you just described it?

A. Yes.

Q. Now, on Wednesday, you make a comment, you were discussing it in the PT studies, you referred to an LCMS device. Just, what does that stand for, the LCMS?

A. LCMS?

Q. Right.

A. Okay. That's a --

Q. Liquid chromatography?

A. -- liquid chromatography mass spec device. That's what we used for all our blood studies.

Q. Now, Dr. Johnson, with respect to the Wands factors, your evaluation of the prior art, you know, the breadth of the claim, everything else that's under the Wands factors, and going through all these iterations with respect to dosage development, now, did you reach any opinions overall as to whether or not undue experimentation is required to practice the full scope of the claims of the '590 patent?

A. Yes.

Q. And what is your opinion in that regard?

A. My final conclusion is that as of January 11, 1995, the filing date of the '590 patent, undue experimentation would have been required by one of ordinary skill in the art to practice the invention as broadly as it's claimed in the '590 patent, excluding conventional immediate release capsules and tablets of atomoxetine hydrochloride. Our opinion was reached by assessing the many factual considerations, including but not limited to those factors known as the Wands factors.

MR. PARKER: All right. Dr. Johnson, thank you. I have no further questions.

Yes, we have a couple things to move into evidence, if there are no objections by counsel.

Okay. DTX-1 is already in.

DTX-3. The Defendants move into evidence DTX-3.

MR. BAJEFSKY: Why don't you read off the whole list?

MR. PARKER: Okay.

THE COURT: Well, read off the whole list, but I'm going to have to know if there are any objections in specific.

Are there any objections, do you know, to the documents he's putting in?

MR. LIPSEY: Could I suggest at the break we can go over this and not take up court time?

THE COURT: Fine.

All right. We'll take a 15-minute break.

MR. BAJEFSKY: Thank you, Your Honor.

(Recess taken)

THE COURT: Be seated.

(The witness resumed the stand.)

MR. PARKER: Your Honor, with respect to some of the documents defense would like to move into evidence, at least we've agreed upon, that would be DTX-3, DTX-34, DTX-55, DTX-42, DTX-86, DTX-95, DTX-165, and DTX-166, we'd move into evidence, Your Honor.

THE COURT: Any objection?

MR. BAJEFSKY: Not to those, Your Honor.

THE COURT: Okay. In evidence.

(Defendants' Trial Exhibits 3, 34, 42, 55, 86, 95, 165 and 166 marked in evidence)

MR. PARKER: Now, with respect, Your Honor, this is where we have an issue. Defendants would like to move into evidence Defendant's Exhibit DTX-162, which I believe Plaintiffs have an objection.

MR. BAJEFSKY: Well, Your Honor, we objected during the testimony and you ruled because it was related to the technology in 2007, not to the time 1995, when --

THE COURT: 162?

MR. PARKER: Yes, DTX-162. It's in the witness

binder, Your Honor.

THE COURT: And what was the objection?

MR. BAJEFSKY: The objection, the issue, Your Honor, in this case is whether in 1995 --

THE COURT: Right.

MR. BAJEFSKY: -- one of ordinary skill in the art would have been able to make these dosage forms. That document reflects 2007. It is not related to the technology in 1995.

MR. PARKER: Well, Your Honor, just by way of example, the issues with atomoxetine as they're identified in 2006 really reflected what they would have been in 1995 as well. I mean, it was a bitter-tasting compound; that was the same in 2006 as it was in '95. To the extent that it was high -- you required high dose to form a transdermal patch, that was probably -- I mean, that was the situation in '95.

Another example, too, Your Honor, it mentions extensive metabolizers, poor metabolizers. That was well known in the prior art. That was the Farid article in terms of the various populations that metabolized atomoxetine.

So really what it's reflecting is, they're identifying formulation challenges that atomoxetine would present, and these challenges are really a reflection of the compound.

THE COURT: Well, these are Eli Lilly's documents.

MR. PARKER: Yes, they are.

THE COURT: Okay. What were these prepared for? Where did these documents come from?

MR. PARKER: They came from -- well, they were produced from Lilly's files.

THE COURT: No, I know that; but why were they produced in 2006 or whatever? What's the origin of these documents?

MR. PARKER: This is what's called a line extension document, Your Honor. During deposition testimony, these were various dosage forms that Lilly was going to consider. Now, what I mean by line extension, companies have a drug, and they want to formulate it into a different form, a patch or a sustained release, controlled release, whatever, and this document was really a reflection of Lilly's consideration of the various dosage forms where they could take atomoxetine beyond the immediate release tablet. And this was an assessment of that, and we have deposition testimony to that effect, and they would rule out certain ones and they would consider other ones as a possibility. So that's all directed to the formulation.

MR. BAJEFSKY: Your Honor, that is not an accurate characterization of what the document reflects.

The individual who testified about it -- there was

no one who really had knowledge of the document's creation, but the individual who testified about it said this was a standard list of dosage forms which would apply to almost any, potentially to any drug, and it was not necessarily ones that they were considering for atomoxetine.

THE COURT: And it was prepared when?

MR. BAJEFSKY: In 2007, Your Honor.

THE COURT: Well, was it prepared in 2007 to discuss that which occurred in '95?

MR. BAJEFSKY: No, Your Honor, it was -- it related to potential line extensions of the product after 2007.

THE COURT: All right. I'll sustain the objection.

Next?

MR. PARKER: Your Honor, with respect to the slides that were shown, we had slides that were the schematics that we went through. We would like to move those into evidence as well.

THE COURT: What's the objection to those?

MR. BAJEFSKY: Your Honor, we had agreed previously on the demonstratives to defer on those, and the parties will try to reach an agreement as to all demonstratives.

THE COURT: All right. Then we'll hold those in

abeyance.

What else?

MR. PARKER: I guess that applies to all the slides that were shown in connection with Dr. Johnson's testimony?

MR. BAJEFSKY: Yes.

MR. PARKER: Okay. We'll hold it in abeyance -- Your Honor will hold it in abeyance.

THE COURT: Okay. Ready to proceed?

MR. BAJEFSKY: I am, Your Honor.

THE COURT: Let's go. We'll go to around four.

MR. BAJEFSKY: Excuse me?

THE COURT: We'll go to around four.

(The witness resumed the stand.)

CROSS-EXAMINATION

BY MR. BAJEFSKY:

Q. Good afternoon, Dr. Johnson.

THE COURT: Do you think you can finish by then?

MR. BAJEFSKY: I don't think so, Your Honor.

(Laughter)

MR. BAJEFSKY: I promise to be shorter than the direct, but --

Q. Dr. Johnson, I'd like you to start by looking at PTX-1, which is tab one in your book. It's the '590 patent.

And first of all, you have been -- I'll let you

get it.

THE COURT: Are you going to be putting most of these documents up on the screen?

MR. BAJEFSKY: Yes, Your Honor.

THE COURT: You know, Doctor, I would suggest, unless you just have some abiding desire to look at the books, since you have so little room over there to manipulate, you may be just as well off, unless you need something to refer to, just looking at the screen. It might be easier for you. But certainly if you want to look at the documents, you can.

Go ahead.

BY MR. BAJEFSKY:

Q. Okay. If we could turn to claim 1, and as you have stated on numerous occasions, that claim defines "a method of treating ADHD by administering an effective amount of atomoxetine to a patient"; correct?

A. Correct.

Q. Okay. Now, during the direct, you identified portions of the specification which you stated described dosage forms in the patent, but you didn't look at the whole paragraph there, did you, Doctor? If you look at column 2, in the second full paragraph -- can we bring that up? -- that paragraph says about dosage forms a little bit more than just simply identifying several dosage forms; is that

correct?

A. Correct.

Q. And it indicates in the first sentence that "Since tomoxetine is readily orally absorbed and requires only once daily administration, there is little or no reason to administer it in any other way than orally." Is that correct?

A. Yes.

Q. And did you consider that in rendering your opinion?

A. Yes.

Q. And the last sentence indicates that it is substantially always preferred, however, to administer tomoxetine as a tablet or capsule, and such pharmaceutical forms are recommended?

A. Yes.

Q. You see that?

Now, you agree that immediate release atomoxetine hydrochloride capsules and tablets are enabled.

A. Yes.

Q. And, in fact, you agree that immediate release tablets and capsules containing atomoxetine, not just atomoxetine hydrochloride, are enabled?

A. No, I don't think I do.

Q. You don't. Okay.

A. Because I think specifically we said atomoxetine

hydrochloride were enabled because that's where the data -- there was prior art data referring to the hydrochloride.

Q. Okay. Let's look at your expert report, Doctor. We'll turn to DTX-168, paragraph 18, which is on page four.

In the last sentence, you say: "In my opinion, the '590 patent specification failed to enable one of ordinary skill in the art to make the dosage forms commensurate in scope with the claims of the '590 patent without undue experimentation, excluding conventional immediate-release tablets and capsules."

A. Right.

Q. And that was in your report?

A. Yes.

Q. And let's look at your -- and there was no limitation as to hydrochloride, was there, Doctor?

A. No.

Q. And you agree, Doctor, -- well, one other question, Doctor.

You have the patent back up there? Can we go back to PTX-1?

You mentioned the injectable -- if we go to column 2 and the same paragraph we were looking at, you mentioned the injectable solutions, depot injections, and suppositories --

A. Right.

Q. -- in your testimony?
A. Correct.
Q. And they appear in a sentence which states: "It may usefully be administered, if there is any reason to do so in a particular circumstance..." is that correct?
A. Correct.
Q. And, Doctor, you agree that the dosage forms that the patent states as substantially always referred are enabled; is that correct?
A. Yes.
Q. And are you aware of any patient, Doctor, who could not be treated for ADHD by administering orally administering atomoxetine hydrochloride immediate release capsule or tablet?
A. There are probably a substantial number of number that really reject it.
Q. Are you aware of any in particular?
A. I would have no way of knowing.
Q. I'm sorry. What?
A. My experience is -- I've had a lot of experience in making children's dosage forms.
Q. Have you ever been -- you're not a doctor, are you, sir?
A. No.
THE COURT: Not a medical doctor.

THE WITNESS: No.

Q. And you've never treated anyone with ADHD.

A. No.

Q. And so you're not aware of any patient who, in fact, could not be treated, any patient with ADHD who, in fact, could not be treated using atomoxetine hydrochloride immediate release capsules or tablets; is that correct?

A. Correct.

Q. Correct?

A. Correct.

Q. And isn't it a fact, Doctor, that in 1995, all pharmaceuticals that were approved for use in the treatment of ADHD were capsules or tablets?

A. I think it was. I'm not sure. There may have been a sustained release tablet in '95. I simply don't know.

Q. But they were all capsules or tablets.

A. I believe so.

Q. Now, do you know of any patient with ADHD that required a depot injection for treatment?

A. No.

Q. In fact, you do not believe that there is any reason why someone would use a depot injection in children when an oral dosage form is available; is that correct, Doctor?

A. Probably -- probably correct.

Q. And do you know of any patient with ADHD that requires

suppository for treatment?
A. No. I'm not a clinician. I'm not treating these patients, so there's no way I'd know of these things.
Q. And you don't know of any patient with ADHD that required a suspension for treatment, do you, Doctor?
A. No.
Q. And you don't know any patient with ADHD that required an injectable solution for treatment, do you, Doctor?
A. No.
Q. And, in fact, you agree that an injection is not the type of dosage form that would be used for a drug that is administered daily.
A. Yes.
Q. And you also agree that an IV injection is not an appropriate dosage form for administering a drug for treating ADHD.
A. Yes.
Q. And, Doctor, you do not know of any patient with ADHD that requires sustained release atomoxetine solid dosage form treatment.
A. I don't know any patients.
Q. And, in fact, according to the patent, the '590 patent, as we looked at before, atomoxetine only requires once-a-day administration.
A. That's what it states.

Q. So there would be no reason for sustained release; isn't that true, Doctor?
A. From the data I've seen, I think sustained release is appropriate.
Q. And what data is that, Doctor?
A. Well, looking at the Farid data and just the general indication that there's nausea problems, the release -- looks like it was -- some of the early, the Zerbe paper, in fact, the drug is released, there's a lot of nausea things like that. So what you would probably try to do is modify the release to some extent so it would be less irritating and cause less problems.
Q. And you don't know of any patient with ADHD that required an atomoxetine transdermal patch treatment.
A. No, I don't know patients.
Q. And you don't know of any patient with ADHD that required a form of atomoxetine other than the hydrochloride salt in treatment, do you, Doctor?
A. I don't know any patients.
Q. And, Doctor, you're aware that all of the Defendants in this lawsuit are proposing to make immediate release capsule formulations of atomoxetine.
A. Yes.
Q. And none are proposing to make any other form of atomoxetine for treatment of ADHD.

A. At this -- I have no knowledge of any other plan.
Q. Now, when you talked about depot injections this morning, you mentioned that, you talked about time periods of seven days or one month for the depot injections. Are you aware of any ADHD treatment that's on the market even today that has an administration time of seven days or one month?
A. No. I don't know the Ritalin -- I don't know how the methylphenidate patch, if that's a daily patch, I don't know how long it lasts.
Q. Doctor, I asked you a series of questions where I said you don't know about any patient taking certain dosage forms, and your answer was no. The answer was, I take it, no, I don't know such patients?
A. I don't know such patients.
Q. Okay. Let's talk about -- let's bring up PTX-1 again and the claims, claim 1, if we can.
Now, as we've said over and over again or has been said today, claim 1 defines a method of treating a specific disease; is that correct?
A. Yes.
Q. And that's ADHD ; right?
A. Correct.
Q. And it's with a specific compound, atomoxetine; is that right?

A. The effect of atomoxetine, I don't know what salt they were using, if they're using a salt or what.

Q. Now, claim 1 does not require any particular dosage form; is that correct?

A. That's correct.

Q. And there's no dosage form recited in the claim, is there, Doctor?

A. No.

Q. And there's no dosage form recited in any of the claims of the '590 patent, is there, Doctor?

A. No.

Q. None of the claims mention a dosage form, do they?

A. No.

Q. Let's look at the specification of the patent and turn to the summary of the invention, first of all.

And the summary of the invention as the claims do simply defines the invention as a method of treating ADHD by administering atomoxetine; is that correct?

A. Pardon me?

Q. The summary of the specification in essence --

A. Yes. Yes.

Q. -- says it's a method -- the invention is a method of treating ADHD by administering an effective amount of atomoxetine.

A. Yes.

Q. And there's nothing in the specification that states the invention involves a new dosage form, is there, Doctor?
A. Could you repeat that question?
Q. Sure.
There's nothing in the specification of the '590 patent that indicates that the invention involved in that patent is a new dosage form; is that correct, Doctor?
A. It doesn't define the dosage form in the claims. However, in the specifications, it lists a variety of dosage forms, all of which may be used to treat ADHD.
Q. Doctor, does the specification of the '590 patent indicate that any of the dosage -- that any dosage form is -- strike that.
Does the specification of the '590 patent state in any place that the invention itself is a new dosage form?
A. No, but to utilize it, you have to use a dosage form.
Q. I understand that. But it doesn't indicate that the invention is a new dosage form.
A. No.
Q. Now, Doctor, I'd like to for a minute just talk a little bit about what you did in preparing for your role as an expert.
Am I correct that you did no work to determine if atomoxetine had any properties that would create formulation problems?

A. I don't have any compound. I did no laboratory work.
Q. And the only research that you did on the properties of atomoxetine and whether it would have any formulation problems was an Internet search?
A. I did brief Internet searches. I did not search in detail.
Q. And, in fact, the only properties that you found at the time you wrote your -- or adopted Dr. Shukla's expert report and at your deposition was that atomoxetine was probably going to be bitter and that the base would probably oxidize; is that correct?
A. Repeat the front end of that again.
Q. Sure.

The only property that you had identified at the time you adopted Dr. Shukla's expert report was that atomoxetine might have a bitter taste and that the base may oxidize?
A. That's the only one I identified. However, I worked with a variety of compounds that had similar structures. There's propylamines, there's pseudoephedrines, there's phenylproplyamines, there's propanol. There's all types of these tablets that I worked for for 40 years. So I had a pretty good idea that there would be some problems, and I think I can identify what those problems were.
Q. But you didn't identify any of those problems in your

expert report, did you, Doctor?

A. I think the expert report identifies a number of problems that have to be solved to actually prepare these dosage forms.

Q. The expert report dealt with general problems. I'm talking about the problems with -- specific problems as to atomoxetine. At the time you wrote your expert report, you had not identified any problems other than potential bitter taste and potential oxidation of the base. Isn't that correct?

A. No, there were -- metabolizers were different. You had poor metabolizers, you had slow and fast metabolizers. That's certainly a dosage form development problem.

Q. Doctor, do you have your deposition transcript in front of you?

We'll put it up on the screen.

MR. BAJEFSKY: Could you put up page 53, lines 7 to 17?

Q. Do you recall, Doctor, at your deposition, I asked you:

"And did you find anything that would indicate that it had -- that it would -- that some -- any particular property or any constellation of properties would create formulation problems?

"ANSWER: Yeah. It was -- it was probably going

to be bitter.

"QUESTION: Okay. Aside from that?

"ANSWER: The base would probably oxidize.

"QUESTION: Okay. Anything else?

"ANSWER: Not that I recall right now."

Did I ask those questions and did you give those answers?

A. Yes.

Q. And as far as the bitter taste goes, Doctor, you never made any effort to determine if that bitter taste could be masked, did you?

A. No.

Q. And you don't know whether or not it could, in fact, be masked with regular syrups, conventional syrups?

A. I'm pretty sure it can't because I've worked with pseudoephedrine, we've made children's products with pseudoephedrine. We had to do different things to make it palatable.

Q. I'm sorry, you're --

A. I worked with similar compounds, and I had to coat those to make them palatable.

Q. Okay. You have your deposition in front of you?

MR. BAJEFSKY: Could we go to page 154? I mean, I'm sorry, line 19 to 23.

Q. And I asked you the question:

"Okay. So you don't know, sitting here today, whether or not it could, in fact, be masked with regular syrups -- conventional syrups?

And you answered, "I don't know."

Do you recall I asked that question, you gave that answer?

A. Yes. Yes.

Q. Doctor, I'd like to talk a little bit about your background.

And if we could bring up PTX-1412, which is your CV.

Go to the next page.

And I want to focus initially on your employment in industry when you were with Schering-Plough and Ayerst.

Now, throughout that entire time period, you were involved in formulating pharmaceutical products; is that correct?

A. Correct.

Q. And am I correct, Doctor, that in those 28 years in industry involved in formulation work, this complex formulation work, that you received one patent?

A. Yes.

Q. And that patent --

MR. BAJEFSKY: Can you put up PTX-1411?

Q. Is this the patent you received, Doctor?

A. Yes.
Q. And it's a patent on a method of protecting against jellyfish stings?
A. Correct.
Q. And you got that patent at the end of your career at Schering?
A. Right.
Q. Now, you testified on direct while you were at Schering-Plough you managed over-the-counter products, suncare products, and Dr. Scholl's products?
A. Yes.
Q. Now, you're a consultant for Atlantic Pharmaceuticals?
A. I have been, yes.
Q. You have been? You still are?
A. I'm not retained. He doesn't pay me. He calls me. He doesn't pay me.
(Laughter)
A. Well, I've worked with him -- we've worked together on a number of projects, so he still feels obligated to call me.
Q. Can we bring up PTX-413, which is tab one in your book?
You recognize this as a web page for --
A. Yes, that's it.
MR. BAJEFSKY: Okay. And if we can bring up

Dr. Johnson's bio, which bridges the bottom of the first page and also the second, top of the second page.

Q. And about four lines from the bottom on the first page, it says: "While at Schering-Plough he was responsible for the development of several skin care products, including Coppertone Sport, Coppertone Water Babies, Coppertone Kids, and other unique and international sun and skin care products."

A. Right.

Q. Does that accurately describe what your responsibilities were at Schering-Plough during that period?

A. Well, we had hundreds of projects. That's -- that's some of those.

Q. But those are the ones that you felt were most significant.

A. I have no -- I've never seen this before.

MR. PARKER: Your Honor, just, if I may, objection. He's already been qualified as an expert. I don't know the relevance of going into his background.

THE COURT: No, no, merely because he's qualified as an expert, that doesn't mean that someone still can't discuss his qualifications. He's not challenging them, but I assume he's pointing something out; and sometimes, things can be pointed out that won't necessarily negate someone being an expert but still could have other points of

interest.

MR. PARKER: Thank you, Your Honor.

THE COURT: But no, he just said he had nothing to do with this.

Correct?

THE WITNESS: I've never seen it. I think some of this is abstracted from -- oh, some of this looks like it's abstracted from NIH grants we made, like the last part here, the --

THE COURT: But my point is, you didn't edit, author it.

THE WITNESS: I didn't see the edit.

THE COURT: Go ahead.

BY MR. BAJEFKSY:

Q. Now, Doctor, in your testimony on Wednesday, you indicated that you were highly knowledgeable about suppositories.

A. Correct.

Q. And today, you testified that you were highly knowledgeable about transdermal delivery systems.

A. Right.

Q. But isn't it true, Doctor, that you don't consider yourself an expert in either one of those dosage forms?

A. I consider myself highly knowledgeable. I'm not somebody that you could put at the bench and formulate the

suppositories. You pick somebody that's been doing that for three or four years. So for the laboratory skills, no, but for the product development skills, yes. I know the steps. I've done it hundreds of times.

Q. Doctor, isn't it true that in your expert report, you did not include transdermal systems or suppositories in your description of your expertise?

A. I don't believe I did. I don't believe I did or not. I don't recall.

Q. Do you have the deposition in front of you?

Page 41, lines six to 17. And I say, and I ask the question:

"Okay. If you would look at Paragraph 8 of your expert report. Now, as I've read it, you -- you list the expertise that you have in this paragraph, right?

"ANSWER: Yes.

A. Correct.

MR. CLEMENT: Objection.

THE COURT: What's the objection?

MR. CLEMENT: Your Honor, it's improper impeachment. That's not an inconsistent statement. He just said he was not -- it's not an inconsistent statement.

THE COURT: First of all, we're going to hear from you (indicating Mr. Parker), not anybody else during objections. The person that does the questioning does the

objection.

Next, I'm not positive what he said vis-à-vis his expertise.

What did you say to that first question?

THE WITNESS: The question --

THE COURT: No, forget that for a second.

THE WITNESS: Oh, okay.

THE COURT: Let me hear his other question read back.

THE WITNESS: Let me hear what I thought.

(Record read)

MR. BAJEFSKY: I'm refreshing his recollection now.

THE COURT: But wait a second. He didn't say that -- I assume you're trying to get him to say that he did not.

MR. BAJEFSKY: Correct.

THE COURT: Well, he said he did not, or, I don't recall.

MR. BAJEFSKY: Let's pull up his expert report. He says he doesn't recall.

THE COURT: Do you recall?

THE WITNESS: No, what I was trying to -- trying to say is that I think when I was asked the question here, today, it had -- am I highly knowledgeable? Yeah, I'm highly knowledgeable in developing most any dosage form or

system. Have I spent years on the bench so I would know every aspect of formulating a -- one of these -- one of these dosage forms? No. But I -- on most of them, I have, but at least two, I did not.

So I think when you asked me this, I didn't consider myself an expert. But I am highly knowledgeable.

BY MR. BAJEFSKY:

Q. Doctor, you've never been -- you have never had any involvement in formulating a drug design to treat ADHD, have you?

A. No.

Q. And as far as your -- on a slightly different topic, your position at the University of Tennessee, it is not a tenured position, is it?

A. No.

MR. BAJEFSKY: Your Honor, can I turn the tab to the reference, PTX 555? Fifty-five, I'm sorry. 55, DTX.

Q. I just want to touch on the Chouinard reference briefly, Doctor. You talked about it in your direct.

Now, this publication reports the use of atomoxetine hydrochloride in clinical trials; is that right?

A. Correct.

Q. And the atomoxetine was administered orally in the form of capsules?

A. Correct.

Q. And if you look at -- let's go to DTX-95, tab three.

Let's go to the first page of that.

Now, you also talked about the Farid article, and this article also discusses clinical trials with atomoxetine hydrochloride?

A. Yes.

Q. In capsule form?

A. Correct.

Q. And it describes, if you turn to the second page -- third page, I'm sorry, third page, in Figure 2, that's a PK analysis? Is that correct?

A. Well, that's the mean plasma concentrations of the metabolite as well as tomoxetine.

Q. Excuse me?

A. It's the mean plaza concentrations of the tomoxetine and nortomoxetine, the metabolite.

Q. And it's the result of an assay reported in this publication?

A. Correct.

Q. And that assay tells one skilled in the art how to measure the blood levels of atomoxetine?

A. Correct.

Q. And it tells you how to measure the blood levels of atomoxetine metabolites?

A. Yes.

Q. And that assay could be used to assay the blood levels of atomoxetine with different dosage forms; correct?

A. If it's reproducible, yes.

Q. I'm sorry, I didn't hear your answer.

A. If it's reproducible, yes, it would.

Q. And you have no reason to doubt it's reproducible.

A. I really can't evaluate it.

Q. You can't what?

A. Evaluate the assay method. I would have an analytical chemist review it.

Q. Because you don't consider yourself an expert in analytical chemistry.

A. I'm not an analytical chemist, no.

Q. By the way, Doctor, you talked about the '081 patent --

A. Correct.

Q. -- in your testimony, and that's DTX-3. And you talked about the number of potential salts that were described in that patent; is that correct?

A. Correct.

Q. And that patent issued in February of 1982?

A. Yes.

Q. And if we go back to the Chouinard publication, DTX-55, --

A. Okay.

Q. -- that was published in 1984?
A. Right.
Q. And it describes a specific salt for atomoxetine?
A. I don't think the specific salt was described, is it?
Yeah, it is. It's hydrochloride.
Q. Let's look at the first sentence.
A. Yes. I see it.
Q. And if we look at Farid, which is DTX-95, that was published in 1985?
A. Correct.
Q. And that also focuses on a specific salt of atomoxetine.
A. Yes.
Q. The hydrochloride salt.
A. Correct.
Q. So in the subsequent publications, they focus on a specific salt of atomoxetine.
A. Well, the Farid and Zerbe are the same study, I think. I'm not sure what other publications you're referring to.
Q. I'm talking about Chouinard -- however you pronounce it, DTX-55 --
A. No, I've already agreed to that. You said what subsequent publications. I don't know what subsequent --
Q. I'm talking about subsequent to the -- I'm sorry --
A. To the patent? Yes.

Q. To the '081 patent.
A. Correct.
Q. To the '081 patent. So the '081 patent was a general disclosure, and the subsequent publications report clinical investigations -- so the subsequent publications, Chouinard and Farid, report clinical testing of atomoxetine hydrochloride.
A. Correct.
Q. Which is much more advanced in the general disclosure in the '081 patent.
A. Correct.
Excuse me. Clarify what is much more -- what was the word --
THE COURT: "Advanced."
A. -- advanced. What do you mean by much more advanced?
MR. BAJEFSKY: Your Honor did you say we were going to four, or 4:30?
THE COURT: Four.
MR. BAJEFSKY: I'm starting a new --
THE COURT: Well, can you answer that question he just had?
MR. BAJEFSKY: I'm sorry.
THE COURT: I don't think he understood what you meant by much more advanced.
MR. BAJEFSKY: Oh, okay.

Q. In the '081 patent, --

A. Right.

Q. -- that was a generic disclosure of a whole bunch of compounds, right?

A. Yes.

Q. And it had a long list of salts in the specifications --

A. Correct.

Q. -- not necessarily associated with atomoxetine.

A. Correct.

Q. And in the subsequent publication, where they're reporting on clinical work, they're reporting a specific salt of atomoxetine has been selected --

A. Correct.

Q. -- to move the compound into clinical studies.

A. Yes.

Q. And in order to get it into clinical studies, the compound had been studied in the ways that you pointed out in the various flow charts you had there; right?

A. Right.

THE COURT: Okay? Does that answer your question?

THE WITNESS: Yes.

THE COURT: All right.

How long do you think you're going to be with this witness tomorrow? Approximately.

MR. BAJEFSKY: I will try to shorten it. I suspect no more than an hour.

THE COURT: Oh, okay.

What's next after this witness?

First of all, I assume there might be a little bit of redirect, not much, I assume.

MR. CLEMENT: Right, after redirect, we don't have further witnesses. We have the deposition designations we're moving in or offering some exhibits that will go with the --

THE COURT: So that will be your case?

MR. CLEMENT: Well, we have the secondary considerations which we're going to hold in abeyance for rebuttal, but that would be -- yes.

THE COURT: Okay.

So then that being said?

MR. LIPSEY: First of all, we think they have an obligation to put their case-in-chief in, whatever it is.

THE COURT: But I've made a ruling with respect to the commercial situation.

MR. LIPSEY: True, and except to the extent that it's appropriate rebuttal, I assume that is what they will put in.

THE COURT: But that's what he just said.

MR. RAKOCZY: Your Honor, Bill Rakoczy.

It is Lilly's burden to put on any secondary consideration that they believe exists. That's the law, and that's what we intend to do pursuant to Your Honor's ruling.

THE COURT: Okay. That begs the question.

MR. LIPSEY: We have Dr. Pliszka, who will be our first witness.

THE COURT: I just want to make sure that we have our witnesses.

MR. LIPSEY: Oh. Yes. We have them.

THE COURT: That's all I care about.

MR. LIPSEY: We have two, actually, Your Honor. We have plenty of witnesses.

THE COURT: I want to make sure we cover the day.

MR. LIPSEY: I think we can.

MR. RAKOCZY: The day will be covered.

Your Honor, may I ask for a quick clarification?

THE COURT: Yes.

MR. RAKOCZY: Every attorney at this table represents a different company Defendant. We have obviously been dividing duties up so we don't duplicate.

YOUR Honor mentioned something about only one objection.

THE COURT: Oh, no, no.

MR. RAKOCZY: My concern, for the record --

THE COURT: What I'm saying is, the person that

does the direct examination is going to be -- I'm not going to have seven different lawyers jumping up and down to the next person coming up. And that goes on both sides.

MR. RAKOCZY: Now, Your Honor, during the cross -- during Mr. Burwell's examination, I noticed Mr. Lipsey couldn't help but exercise some type of in loco parentis thing and interject himself into -- I'm not even sure what was going on, Your Honor. I just want to know, what are the ground rules for --

THE COURT: Well, I don't think we should be referring to anyone as loco.

(Laughter)

MR. LIPSEY: Except Mr. Lipsey.

(Laughter)

MR. RAKOCZY: And, Your Honor --

THE COURT: What will occur, if I wasn't clear, I'll be clear now: The attorney that does the questioning will be the attorney that does the objecting thereafter. Otherwise, I'll have things coming from 40 directions. And I'm not going to do it that way.

MR. RAKOCZY: Understood, Your Honor.

THE COURT: Now, if there's something outrageous -- now, he sat back down before. I'm not suggesting somebody can't suggest to the attorney that there might be something that's problematic. But I can't have everybody

jumping up and down. And it goes for both sides. I don't remember Mr. Lipsey doing that, but if he did, he won't do it any more.

(Laughter)

MR. RAKOCZY: Now, in Lilly's case-in-chief, we are assuming that more than one Defendant will have the right to cross-examine the witness.

THE COURT: If you recall, at the beginning of the case, I said, now, what order are we going to go? I'm not precluding any specific Defendant from doing that if that's the situation. That's fine. That's different than having the person doing the direct examination then having everybody else making their objections.

MR. RAKOCZY: Thank you, Your Honor.

MR. CLEMENT: Thank you, Your Honor.

THE COURT: That's a free-for-all, and one thing I don't want to do is a free-for-all.

So back to the original question: We will be covered for tomorrow? That is my point.

MR. RAKOCZY: Yes.

MR. CLEMENT: Yes.

THE COURT: Okay. That said:

You'll have to come back tomorrow. I'm sure you just can't wait.

(Laughter)

THE WITNESS: Please.

What do I do with the books?

THE COURT: What do you do with the books? Leave them there.

We'll see everyone tomorrow morning. We'll start at nine sharp.

Thank you.

(Matter adjourned until Tuesday, March 25, 2010, commencing at 9 a.m.)

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